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Hazard Analysis and Critical Control Point (HAACP); Procedures for the Safe and Sanitary Processing and Importing of Juice; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 120

[Docket No. 97N–0511]

RIN 0910–AA43

Hazard Analysis and Critical Control Point (HAACP); Procedures for the Safe and Sanitary Processing and Importing of Juice

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or the agency) is adopting final regulations to ensure the safe and sanitary processing of fruit and vegetable juices. The regulations mandate the application of Hazard Analysis and Critical Control Point (HACCP) principles to the processing of these foods. HACCP is a preventive system of hazard control. FDA is taking this action because there have been a number of food hazards associated with juice products and because a system of preventive control measures is the most effective and efficient way to ensure that these products are safe.

DATES: Effective Dates: This rule is effective January 22, 2002.

Compliance Date: For small businesses as defined in 21 CFR 120.1(b)(1), the final rule will be binding January 21, 2003. For very small businesses as defined in 21 CFR 120.1(b)(2), the final rule will be binding January 20, 2004.

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SUPPLEMENTARY INFORMATION:

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I. Background

A. Notice of Intent

In the **Federal Register** of August 28, 1997 (62 FR 45593)(Ref. 1), FDA published a notice of intent (hereinafter referred to as the notice of intent) that announced a comprehensive program to address the incidence of foodborne illness related to consumption of fresh juice and ultimately to address the safety of all juice products. In the notice of intent, the agency invited comment on the appropriateness of its strategy to: (1) Initiate rulemaking on a mandatory HACCP program for some or all juice products; (2) propose that the labels or the labeling of juice products not specifically processed to prevent, reduce, or eliminate pathogens bear a warning statement informing consumers of the risk of illness associated with consumption of the product; and (3) initiate several educational programs to minimize the hazards associated with consumption of fresh juices. The agency stated that it would address comments received within 15 days of publication of the notice of intent as part of any rule proposed by the agency. FDA also stated that it would consider all comments to the notice of intent received after 15 days in any final rulemaking. FDA reviewed all of the comments received within 15 days of publication and found that they provided no information that would cause the agency to conclude that the HACCP proposal was inappropriate. Comments received 15 days after publication of the notice of intent are discussed in this final rule.

B. The Proposal

In the **Federal Register** of April 24, 1998 (63 FR 20450) (Ref. 2), FDA published a proposed rule to establish requirements relating to the processing of juice and juice products (hereinafter referred to as the HACCP proposal).[1] The proposal would have required the application of HACCP principles by processors and importers to ensure juice safety to the maximum extent practicable. FDA proposed these regulations because there had been a number of food hazards, including some directly affecting children, associated with juice products. The agency tentatively concluded that the most effective way to ensure the safety of juice products is to process the products under a system of preventive control measures based on HACCP principles. Interested persons were given until July 8, 1998, to comment on the HACCP proposal. The agency subsequently extended the comment period to August 7, 1998 (63 FR 37057; July 8, 1998) (Ref. 3).

In addition to publishing the HACCP proposal, FDA published in the same issue of the **Federal Register** (63 FR 20486) (Ref. 4) a proposed rule (the juice labeling proposal) to require warning labels on juice that has not been processed to prevent, reduce to acceptable levels, or eliminate pathogens that may be present. As fully discussed in the juice labeling proposal, FDA proposed that untreated juice products bear a warning statement informing at risk consumers of the hazard posed by untreated juices to allow them to make informed decisions on whether to purchase and consume such products. The labeling proposal was finalized on July 8, 1998 (63 FR 37030) (Ref. 5).

FDA issued in the **Federal Register** of May 1, 1998 (63 FR 24254) (Ref. 6) a single Preliminary Regulatory Impact Analysis (PRIA) that addressed both the

[1] As defined in §120.1 (21 CFR 120.1) "juice" refers both to beverages that are composed exclusively of an aqueous liquid or liquids extracted from one or more fruits or vegetables and to the juice ingredient in those beverages that contain other ingredients in addition to juice. In this document, the term "juice product" refers both to beverages that contain only juice and to the juice ingredient of beverages that are composed of juice and other ingredients.

In the remainder of this document, products not processed to prevent, reduce, or eliminate hazards will be referred to as "untreated juice products." In addition, processing to "prevent, reduce, or eliminate" hazards will be referred to as processing to "control" hazards.

juice labeling proposal and the juice HACCP proposal. Interested parties were given until May 26, 1998, to comment on aspects of the PRIA relating to the juice labeling proposal and until July 8, 1998, to comment on aspects of the PRIA relating to the juice HACCP proposal.

C. Additional Opportunities for Public Participation

Under the juice labeling rule (§ 101.17(g) (21 CFR 101.17(g))), juice and juice products that have not been specifically processed to attain a 5-log reduction in the pertinent pathogen must bear a warning label. Similarly, under the juice HACCP proposal (proposed § 120.24), covered processors must attain a 5-log reduction in the pertinent pathogen in their HACCP systems. Accordingly, in November 1998, FDA held two technical workshops on how processors could attain a 5-log (*i.e.*, 10^5) reduction in the pertinent pathogen in citrus juices (63 FR 57594; October 28, 1998) (Ref. 7). The transcripts from the two workshops were placed on display in the docket for the juice HACCP proposal and on the FDA/CFSAN website http://www.fda.gov/). On December 17, 1998 (63 FR 69579) (Ref. 8), the comment period for the juice HACCP proposal was reopened until January 19, 1999, to allow public comment on data and other information that were presented at or developed as a result of these workshops. In addition, FDA expressly sought comments on the following four specific topics related to the application of the 5-log pathogen reduction standard: (1) Appropriate baselines for the calculation of the 5-log pathogen reduction; (2) feasible interventions or practices for the cultivation and harvest of fruits and vegetables, and acquisition of supplies and materials that may contribute to achieving a 5-log pathogen reduction; (3) feasible interventions for the production process that may contribute to achieving a 5-log pathogen reduction; and (4) acceptable methods for measuring and validating 5-log reductions.

On July 15 and 16, 1999, FDA held a workshop on food safety controls for the apple cider[2] industry (64 FR 34125; June 25, 1999) (Ref. 9). The workshop dealt with issues related to the implementation of the agency's regulations requiring a warning statement for certain juice products. Specifically, the workshop addressed pathogen reduction interventions that may be effective for apple cider production and the methods used to measure and validate such interventions. Results of research conducted by Federal, State, private, and academic institutions were presented.

In the **Federal Register** of November 23, 1999 (64 FR 65669) (Ref. 10), FDA announced the availability of new data and information regarding the safe processing of citrus juice and juice products, and reopened the comment period for the juice HACCP proposal until January 24, 2000, in order to receive comment on the new data and other information. In that same notice, in order to develop the most complete administrative record possible, FDA requested additional data and information relating to four separate areas: Internalization and survival of pathogens in produce used to produce juice, especially citrus fruit; application and measurement of the 5-log reduction standard; current methods used by juice processors to monitor the application of heat treatment to juice; and certain economic matters related to juice regulation. The notice discussed in detail the particular issues in each of the four areas in which the agency was seeking comments (64 FR 65669 at 65670 through 65671). Two of these areas (internalization and survival of pathogens and application and measurement of the 5-log reduction standard) were also to be the subject of the December 8 to 9, 1999, public meeting of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) (discussed in more detail below), and the comment period extension was established so as to permit comments on the identified issues in light of any information or recommendations coming out of that meeting of the NACMCF.

D. NACMCF Public Meeting

NACMCF is an advisory committee chartered under the U.S. Department of Agriculture (USDA) and has members from USDA (Food Safety and Inspection Service), the Department of Health and Human Services (U.S. Food and Drug Administration and the Centers for Disease Control and Prevention (CDC)), the Department of Commerce (National Marine Fisheries Service), the Department of Defense (Office of the Army Surgeon General), academia, industry and State agencies. The NACMCF provides guidance and recommendations to the Secretary of Agriculture and the Secretary of Health and Human Services regarding the microbiological safety of foods.

The NACMCF held a public meeting on December 8 to 9, 1999 (64 FR 63281; November 19, 1999) (Refs. 11 and 12) to discuss recent research and other information related to performance criteria for fresh citrus juices. FDA sought advice from the NACMCF on two issues. In addition, the meeting agenda provided an opportunity for public comment.

First, FDA asked the NACMCF about the potential internalization and survival of pathogens in citrus fruits and citrus juices. The NACMCF members generally agreed that it is theoretically possible for microorganisms to enter the interior of apparently sound, intact citrus fruit under certain conditions (*e.g.*, temperature difference between fruit and wash water), and that human pathogens appear to be able to survive, at least under defined laboratory conditions, in the fruit itself (Ref. 12). However, the NACMCF members concluded, based on the current information, that the potential for microorganisms to enter and survive in intact fruit is not likely to result in a significant public health risk. In particular, the Committee members concluded, based upon the limited data available, including data presented by the industry, that although it is theoretically possible, it is unlikely that pathogens will enter and grow in sound, intact fruit under actual current industry processing practices.

Second, the agency asked the NACMCF about the application and measurement of the 5-log pathogen reduction standard to citrus fruit. In response, the NACMCF outlined the following five basic consensus decisions related to the application and measurement of the 5-log reduction standard to citrus juices:

1. The 5-log reduction need not start with the extracted juice but may begin with the exterior decontamination of citrus fruit. However, processors should not start a cumulative 5-log reduction until after the fruit is cleaned (*i.e.*, washed) and culled (*i.e.*, damaged or dropped fruit is removed so that the remaining fruit is USDA choice level or higher quality).

2. One possible method to minimize potential microbial infiltration into the fruit would be by controlling fruit and wash water temperatures, as well as excluding fruit that is split, punctured, or otherwise not intact. Laboratory studies indicate that microbial infiltration of fruit occurred when warm fruit was washed or submerged into cold water (Refs. 13 and 14).

3. The entire 5-log process must occur under one firm's control and in one processing facility, *i.e.*, all steps from

[2] Although the terms "apple cider" and "apple juice" may have different meanings throughout the United States, these terms are used interchangeably throughout this final rule

fruit receiving to final juice packaging (and all points included in the 5-log reduction process) must occur at one facility. If processors transport fruit or juice to another facility for extraction, blending, or final packaging, the 5-log reduction must be accomplished in the second facility.

4. If the expressed juice is aseptically packaged in a single-use sanitary non-reusable tote (sterile bag in box type package form) and the bulk packed juice will be repackaged at another facility, a 5-log reduction process must be performed on that juice prior to final fill and packaging. If the juice is used directly from the tote (*e.g.*, used to dispense juice and juice beverages at retail), the 5-log reduction process need not be repeated. Because juice in tanker trucks is not juice in a final package form, juice shipped in bulk tankers must undergo a 5-log reduction process after transport and prior to final fill and packaging.

5. As part of a HACCP verification program, firms should conduct microbial testing on the final product if the 5-log reduction process relies in part on fruit surface treatment. This testing would not be batch-by-batch testing for lot acceptance prior to shipping, but would be used to verify the 5-log reduction process. The testing should use generic *E. coli* as a means to assess the control of the process and should be conducted as specified in the HACCP plan, utilizing an appropriate sampling plan. However, if results indicate (*i.e.*, the presence of generic *E. coli*) that the 5-log reduction has not been achieved, processors should consider testing the juice for specific pathogens of concern, such as *Salmonella* or any other microorganisms of concern, according to an appropriate sampling plan and processors should take suitable corrective actions. If the 5-log reduction is applied after the juice is expressed, microbiological testing would not be required as part of a HACCP verification program.

II. Response to the Comments

FDA received approximately 85 responses, each containing one or more comments, to the notice of intent. FDA addressed some of these comments in the juice HACCP proposal. FDA subsequently received approximately 800 responses, each containing one or more comments, to the juice HACCP proposal. Comments received in response to the notice of intent and to the juice HACCP proposal came from industry, trade organizations, consumers, consumer interest groups, academia, and State government agencies. Comments concerning labeling issues are discussed to the extent that they fall within the scope of issues presented by the juice HACCP proposal. Some of the comments supported the proposal. Other comments opposed, or suggested modifications of various provisions of, the proposal. The agency discusses below the significant comments bearing on the proposed HACCP regulation and, when applicable, any revisions to the proposed regulation made in response to these comments. Responses to the notice of intent that bear on the juice HACCP proposal and that were not addressed in that proposal also are addressed in this document. For simplicity, the agency's discussion does not identify comments as to whether they were received in response to the notice of intent or in response to the juice HACCP proposal.

A. Alternatives to HACCP Considered by the Agency

In developing a strategy to address the hazards associated with juice, FDA considered the following alternatives to HACCP: (1) Increased inspections, (2) current good manufacturing practices (CGMP's), (3) mandatory pasteurization, (4) labeling as a long-term solution, (5) education, and (6) an approach that would draw a distinction between untreated apple cider and all other juices. The agency discussed each alternative in the HACCP proposed rule (63 FR 20450 at 20454) and its reasons for proposing the use of HACCP systems rather than the alternatives (Ref. 2). FDA received a number of comments questioning the agency's rejection of certain alternatives. The agency's responses to those comments are set forth in this section (section II.A). To provide a meaningful context for the discussion of the alternatives, FDA is providing the following discussion of HACCP.

HACCP is a focused, efficient, preventive system that minimizes the chance that foods contaminated with hazardous materials or microorganisms will be consumed. The strength of HACCP lies in its ability to enable the processor to identify, systematically and scientifically, the primary food safety hazards of concern for the specific products, the specific processes, and the specific manufacturing facilities in question, and then to implement on a focused, consistent basis, steps (critical control points (CCP's)) in food production, processing, or preparation that are critical to prevent, reduce to acceptable levels, or eliminate hazards from the particular food being processed. Flexibility in how to address identified hazards is inherent in HACCP systems. Even when producing comparable products, no two processors use the same source of incoming materials or the same processing technique, or manufacture in identical facilities. Each of these factors (and their many combinations) presents potential opportunities for contamination of the food. HACCP focuses the processor on understanding his own process and the hazards that may be introduced during that process, and identifying specific controls to prevent, reduce, or eliminate the identified hazards.

The flexibility of the HACCP approach is a critically important attribute. This flexibility allows manufacturers to adjust CCP's, adjust techniques used to address CCP's when changes occur in the system (*e.g.*, use of new ingredients), and readily incorporate new scientific developments (*e.g.*, use of new control techniques, new preventive technologies, identification of new hazards). Another important strength of HACCP is the development of a plan written by the processor detailing the control measures to be used at CCP's. By developing a written plan, juice processors gain a working knowledge of their processing system, its effect on the food, and where in the system potential contamination may occur. Both the processor and the agency are able to derive the full benefits of a HACCP system. The hazard analysis and HACCP plan allow both the processor and the agency to verify and validate the operation of the system. HACCP's flexibility also permits processors to select the appropriate control measures in the context of how the whole system functions, allowing processors to use the most appropriate and economical methods to control food hazards that are reasonably likely to occur in their operation. The ability to choose among various control methods encourages research on and development of new and innovative technologies to better address individual situations. Because of its flexibility, HACCP is particularly advantageous to small businesses and seasonal processors.

HACCP provides the processor with a record of identified food hazards. It allows quick identification of a breakdown in the processing system and thus, prevents products with food hazards from entering the marketplace and causing illness. Moreover, review of records over a longer period of time (days or weeks) may reveal a trend toward a breakdown in the system, such as a critical processing temperature that is slowly drifting down. HACCP records allow evaluation of whether changes in the processing system require changes

in CCP's or their critical limits (CL's), thus ensuring that the HACCP system is up-to-date and adequate to control all food hazards that are reasonably likely to occur. This recordkeeping also allows regulatory investigators to readily review the long term performance of a firm's processing system, rather than relying on a time-limited inspection, which provides only a snapshot of how well the firm is doing in producing and distributing safe product on any given day.

HACCP is ideally suited to respond to emerging problems because a HACCP system is a dynamic system that must be validated periodically to ensure that all hazards reasonably likely to occur are identified and controlled via CCP's. Validation of both the hazard analysis and the HACCP plan entails a thorough review to ensure that all hazards that are reasonably likely to occur are addressed in the HACCP system.

Because of its preventive yet flexible nature, HACCP is recognized by food safety professionals as the single most effective means to assure the safety of foods. It has been endorsed by the National Academy of Sciences (Ref. 15), the Codex Alimentarius Commission (an international food standard-setting organization) (Ref. 16), and the NACMCF (Ref. 17). Increasingly, use of HACCP systems is an indication to importing countries that food safety systems that provide a standardized level of public health protection are in place and being used by producers in exporting countries.

1 Increased Inspection

(Comment 1) Several comments suggested that the increased FDA inspection approach would be preferable to HACCP.

The agency disagrees. FDA's responsibility is to implement and enforce the Federal Food, Drug, and Cosmetic Act (the act), *i.e.*, to oversee the manufacture of safe food. Increased inspection by FDA is a resource-intensive activity that puts the responsibility and burden for ensuring food safety on the agency rather than on the juice processors. Inspections can, of course, provide food processors with valuable information about improving the safety of their products. However, safety cannot be effectively inspected into foods. Rather, food processing systems themselves must be designed and implemented in a manner that results in the production of safe food. Part 120 (21 CFR part 120) provides a flexible standard that both the juice industry and the agency will use to determine the adequacy of a process. HACCP has been shown to be an approach that effectively ensures the production of food that is safe and wholesome (Ref. 17). Importantly, the HACCP approach clearly delineates the processor's responsibility to make safe products and FDA's responsibility to monitor conformance with the act through inspections and record review.

(Comment 2) One comment advocated a short-term solution of increased inspections for adherence to sanitation standard operating procedures (SSOP's) and CGMP's with zero tolerance for noncompliance. Another comment stated that the juice industry would welcome increased inspections as it implements new safety measures.

The agency has been actively monitoring the juice industry, especially the fresh juice industry, in response to recent outbreaks. In addition, FDA has conducted inspections to determine compliance with the label warning statement required by § 101.17(g). The agency will continue this additional oversight of the juice industry during implementation of part 120 until it has assurance that the industry is in compliance.

(Comment 3) One comment suggested that cider operations be inspected and graded for cleanliness by the States, like restaurants.

The agency disagrees with the comment. Although sanitation (*i.e.*, cleanliness) is important in cider and all other food production operations, it is only a starting point for ensuring that safe food is produced and distributed to consumers. This limitation exists regardless of the regulatory agency inspecting for sanitation.

(Comment 4) Several comments suggested that industry-funded inspections could be used to ensure safe juice.

FDA disagrees with these comments. As discussed above, inspections are not an adequate substitute for HACCP. Moreover, the agency does not have the authority to require or accept funds from the industry for inspections of juice processors.

2. Current Good Manufacturing Practices

(Comment 5) Comments maintained that a survey of several small citrus producers and juice bars showed that SSOP's and CGMP's are sufficient to produce safe juice. One comment stated that no additional regulations are needed for dairies that process juice because dairies follow sanitation and other procedures outlined by the National Conference on Interstate Milk Shipments (NCIMS) and the application of these principles affects other products made in these facilities.

The agency disagrees that CGMP's and SSOP's alone are adequate to control microbial hazards in juice although it does believe that CGMP's play an important role in juice safety. The survey referenced by the comment, was conducted by the Florida Department of Agriculture & Consumer Services and found that 17 out of 383 samples analyzed (4.4 percent) were positive for generic *E. coli* and did not indicate what, if any, other microorganisms were present. While generic *E. coli* are not pathogens, their presence is indicative of fecal contamination and may be indicative of the presence of pathogens such as *E. coli* O157:H7. (The significance of fecal contamination is discussed in more detail in the response to comment 143.) Therefore, it is unclear how the comments concluded that CGMP's and SSOP's provide adequate control of potential food hazards to assure the safety of the food by relying on the survey data.

The NCIMS procedures (*i.e.*, the Pasteurized Milk Ordinance (PMO) (Ref.18)) were developed to assure the safety of milk. While there may be some fundamental principles, such as basic sanitation procedures, that apply to both the production of milk and juice, the products are vulnerable to different hazards. Moreover, States administer the PMO, and the agency has no information indicating consistency in the application of the PMO to juice inspections in dairies. Thus, investigators in some States may use the PMO as a guide in conducting dairy juice operations and others may not. Therefore, the agency does not believe that application of NCIMS procedures in some dairies that process juice negates the need for juice-specific HACCP regulations.

(Comment 6) Several comments argued that the examples of nonmicrobial hazards (*e.g.*, tin, lead, nitrates, patulin, glass, or plastic) cited in the juice HACCP proposal are CGMP violations and would not be included in a processor's HACCP plan.

The agency does not agree with the comments. Whether or not a nonmicrobial food hazard jeopardizes the safety of a juice product is determined by the processor during the hazard analysis of his process. If potential nonmicrobial food hazards are not reasonably likely to occur, then the HACCP plan does not need to address these hazards with CCP's. Thus, FDA does not believe that it is reasonable to make a global statement that CGMP's in part 110 (21 CFR part 110) are adequate

to control nonmicrobial hazards in all systems, because that determination must be made by each individual processor through a hazard analysis of the individual system.

(Comment 7) Several comments noted that the risks posed by the nonmicrobial hazards identified by FDA cannot be quantified for economic purposes, that microbial hazards alone are not an adequate basis on which to mandate HACCP, and that CGMP's are adequate.

FDA disagrees with these comments. There are nonmicrobial food hazards that may be reasonably likely to occur in juice. Some non-microbial hazards, such as glass, tin, and copper, present acute risks (Ref. 6), and result in acute illnesses or injuries that generate medical and hospital costs, as well as lost productivity costs.

The adverse health effects of other nonmicrobial hazards are chronic (long-term) in nature. For example, long-term exposure to the mycotoxin, patulin, has been shown to be toxic in safety assessments conducted in the United States (Refs. 19 and 20) and by international organizations (Refs. 21 and 22). Patulin is produced by several species of mold that can grow on apples, particularly if bruised or otherwise damaged, and has been found to occur at high levels in some apple juice products. The long-term toxic effects in young children are of particular concern because children consume larger quantities of apple juice relative to body weight than other age groups. A compilation of data from three surveys showed that nearly one-fifth of the samples of apple juice contained levels of patulin in excess of 50 microgram/liter (µg/L) (Ref. 23), the level recently established by FDA in draft guidance as the maximum level that should be present in foods (Ref. 24).

The agency recognizes that quantifying the economic effects of chronic non-microbial hazards is difficult. Given the difficulties in quantification, FDA chose to not include nonmicrobial hazards with chronic health risks in the PRIA, thereby underestimating the benefits of the proposal. Nevertheless, hazards with chronic health risks exist and the potential effects on health are real. Thus, hazards with chronic health risks must be considered, along with nonmicrobial hazards with acute health consequences and microbial hazards, during the hazard analysis and a determination made as to whether the potential hazard is reasonably likely to occur (comment 63 discusses how a hazard analysis must be conducted) and thus, must be included in the HACCP plan.

(Comment 8) Several comments maintained that the enforcement of CGMP's or sanitation standards would ensure the safety of all juices.

The agency disagrees with the comments. Outbreaks of foodborne disease have been associated with juice despite the fact that the processors appear to have been actively implementing CGMP's. Increased compliance with the CGMP regulations in part 110, including all sanitation provisions, is certainly desirable. However, CGMP's are general in nature and apply to all types of facilities that process all types of food products from highly processed foods to raw foods that are merely packaged and labeled. CGMP's were not designed specifically to address individual production facilities (for juice or any other commodity) or the unique attributes associated with specific foodborne hazards. HACCP systems, as discussed in section II.A of this document, provide focused, product- and process-specific prevention and control of potential hazards. HACCP augments the controls established through CGMP's by: (1) Determining the food hazards that are reasonably likely to occur in a specific facility and process and thus, warrant extra consideration beyond application of routine food safety measures, (2) identifying a specific CGMP or additional control measure that must be undertaken to prevent this food hazard that is reasonably likely to occur from reaching the consumer, and (3) developing a verifiable procedure for assuring that each control measure was applied and was effective. This focused consideration of hazards and their prevention provides a higher degree of safety assurance than application of CGMP's.

3. Mandatory Pasteurization

(Comment 9) Several comments requested that the agency mandate pasteurization or use of a universal thermal process (thermal kill) to ensure juice safety. The comments maintained that mandatory pasteurization is a reasonable, science-based solution that would ensure safe juice, is consistent with FDA's mission to protect the public health, and would assure consumers and regulators that the microbial hazards associated with juice are being prevented in the most effective manner. Conversely, a number of comments opposed mandatory pasteurization. They argued that nutritional value is lost from heat treatment; some consumers prefer unpasteurized juice; pasteurized juice may become contaminated after treatment and still put consumers at risk; and the apple cider and fresh juice industry would be destroyed.

Based upon the available information, FDA does not believe that it is necessary or appropriate to mandate pasteurization or other thermal treatment of juice. The agency is aware of the reasons why processors pasteurize or elect not to pasteurize their juice products. Pasteurization, a heat treatment sufficient to destroy pathogens, is an effective and proven technology that will attain the 5-log reduction in pathogens and, thus ensure microbiologically safe juice. Pasteurization also results in a longer shelf-life of refrigerated juices. With proper post-processing handling, pasteurization assures consumers and regulators that the potential microbial hazards associated with juice are prevented. However, pasteurization is not the only method for addressing potential microbial contamination. This was discussed extensively in the juice HACCP proposal (63 FR 20450 at 20454) (Ref. 2) and again in the juice labeling final rule (63 FR 37030 at 37041) (Ref. 5). This approach is supported by the NACMCF recommendation that FDA establish safety performance criteria for appropriate target organisms rather than mandating a specific intervention technology (Ref. 25). Mandating a specific intervention technology such as pasteurization would limit the development of new, potentially less costly technologies that may be as effective as pasteurization. New nonthermal technologies (*e.g.*, UV irradiation and pulsed light, as approved by FDA; high pressure) may be able to achieve the required pathogen reduction. The use of non-thermal technologies will provide consumers with a greater selection of safe products to purchase. Furthermore, mandatory pasteurization would not control non-microbial hazards in juice. Therefore, FDA is declining to mandate pasteurization for juice.

(Comment 10) One comment stated that pasteurization should be mandatory for apple cider to eliminate a major source of health risks.

FDA disagrees with the comment. Under § 120.24, apple cider processors must treat their juice to achieve a 5-log reduction in the pertinent pathogen. At the present time, the agency is not aware of any technology that can accomplish the 5-log reduction in apple juice products except by treating the extracted juice with a "kill step." However the "kill step" does not necessarily have to be pasteurization. This approach allows for innovation in

the development of new processes to achieve the 5-log pathogen reduction.

4. Labeling

(Comment 11) Two comments suggested that FDA require either pasteurization or a permanent warning label statement for producers who do not pasteurize. One comment stated that FDA should require HACCP with a CCP of either a 5-log performance standard for pathogen reduction or a warning label.

FDA disagrees with the comments. Under § 120.24, juice processors must achieve the 5-log reduction in their juice. As discussed in both the HACCP proposal and in this final rule, it is possible for firms to manufacture juice to achieve this reduction by means other than pasteurization. The alternative presented in the comments, labeling, has some limitations as a public health measure. The effectiveness of labeling untreated juice to alert consumers to possible harmful effects from its consumption relies on consumers' reading, comprehending, and acting on the information in the labeling. Although labeling can provide consumers with the information to make food safety related choices, education is an important factor in a consumer's choice. Therefore, there are limitations to the effectiveness of labeling.

The agency mandated the use of warning label statements on juice largely as an interim step to establishing the HACCP regulation. For most juice products, the warning label is a short term solution. While FDA is reluctant to rely on labeling as the sole safety measure, the agency recognizes that in certain circumstances, labeling may, on balance, provide the most reasonable approach to protect the public health. FDA believes that HAACP, as required in this final rule, is a reasonable approach because, in contrast to some other food safety problems, the facts show that, for juice, processor control of pathogens is reasonably achievable. Moreover, a warning label does not substitute for adequate processing of juice, is not an appropriate substitute for the 5-log performance standard, and would not be considered a CCP for juice under part 120.

For juice produced by retailers (as defined in the rule), however, the warning statement is a long term solution. The agency discussed its reasons for exempting retail establishments from part 120 in the juice HACCP proposal (63 FR 20450 at 20464) (Ref. 2), and these reasons are further discussed in section III.B.2.b of this document. The agency intends to work closely with the States to provide recommendations for implementing measures that will assure safe juice at retail. Therefore, the agency concludes that its current regulations and programs are balanced and appropriate for juice and juice products.

(Comment 12) Several comments asked that FDA make the warning label statement a permanent option because, if it is adequate to ensure consumer safety with products exempt from HACCP, it should be adequate for all juice products.

FDA disagrees with the comments. As noted in the previous response, while the warning label statement may be effective, particularly with consumers aware of juice safety problems, it has limitations as a public health measure. The warning label statement simply informs consumers that the juice bearing the statement has not been treated to control pathogens and that the consumption of untreated juice may pose a risk of illness. As noted, the effectiveness of any warning label relies on consumer education and action. FDA is not changing the warning label statement requirements in this rulemaking.

5. Education

(Comment 13) Several comments maintained that increasing industry education is all that is needed to ensure the safety of all juices.

The agency disagrees. While FDA supports and encourages processor education as a way to improve the safety of the food supply, such measures alone, without being teamed with implementation of an effective food safety control program, such as HACCP, and government oversight, will not ensure consumer protection from hazards that may be present in juice. Training and education is only one step in the effective implementation of any food safety system, including HACCP. Effectively, this final rule requires the industry to improve their education in food safety in order to implement effective HACCP systems. Implementation of an effective HACCP system demonstrates a processor's understanding of HACCP principles and the ability to translate theory into production of safer food. Therefore, the agency concludes that increased industry education alone would not be sufficient to ensure the safety of all juices.

6. Alternative Approach

(Comment 14) Many comments supported the alternative approach outlined in the proposed rule (63 FR 20450 at 20456) (Ref. 2) that would: (1) Require producers of apple cider to choose between HACCP with a performance standard and labeling and (2) require processors of all other juices to choose between HACCP, a performance standard, and labeling.

The agency has evaluated the alternative approaches and concludes that HACCP with a performance standard is the most effective and efficient approach to ensure safe juice. FDA notes that no data or other information were submitted to persuade the agency that the alternative approach described in the proposal would provide adequate public health assurance as would be provided by the HACCP regulation set forth below. Although more outbreaks have been traced to the consumption of apple juice than other juices, a fact reflected in the proposed alternative approach, the agency concludes that, because microbial, chemical, and physical hazards may occur in all juices, and outbreaks have been associated with a variety of juices, there is a need to regulate all juices in the same general manner. Furthermore, the performance standard and the label warning statement only address microbial hazards. In contrast, HACCP systems address physical and chemical, as well as microbiological, hazards, thus providing greater assurance that juice is safe. Therefore, the agency is requiring that all juice processors with the exception of those specifically exempted by § 120.3(j)(2) use HACCP systems as set forth in part 120.

B. Response to the Decision to Propose HACCP

FDA proposed to require HACCP for juice products because it had tentatively concluded that HACCP was an appropriate system of preventive controls necessary to produce safe juice products. The evidence presented in the proposal demonstrated that juice has been a vehicle for pathogens that have caused a number of foodborne illness outbreaks. While pathogens can be controlled through heat treatment, the data (Ref. 2) clearly demonstrate that there are potential nonmicrobiological hazards associated with juice that cannot be controlled through heat treatment. For these reasons, FDA tentatively concluded that a HACCP program that addresses all potential hazards (*i.e.*, microbiological, chemical, and physical), allows each juice manufacturer to evaluate its own process, and to institute appropriate controls for all hazards identified as reasonably likely to occur in that manufacturer's process should be established.

(Comment 15) Several comments advocated HACCP limited to pathogen control.

The agency disagrees with the comments. While pathogen control is a significant part of any HACCP system for juice, there are potential chemical and physical hazards that can occur in juice, with significant public health implications, and these hazards may be most effectively controlled through application of HACCP (Ref. 2). HACCP provides a way to focus on specific CCP's addressing specific hazards, both microbial and non-microbial (*e.g.*, tin, lead, nitrates, patulin, glass, or plastic) that are relevant to juice processing operations and products. These hazards may be appropriately identified in the hazard analysis as hazards that are reasonably likely to occur and controlled through a HACCP plan.

There are a number of potential hazards for juice that are nonmicrobial in nature. For example, juice products have become contaminated with cleaning solution. If this contamination is a hazard that is reasonably likely to occur in a particular process (*e.g.*, there is a repeated history of its occurrence), the processor must establish controls in its HACCP plan to prevent the contamination rather than address the contamination in their SSOP's.

Similarly, some juice products have been recalled due to the presence of glass. Glass shards in juice represent a severe and acute public health threat. Processors who package in glass must consider whether glass in their final product is reasonably likely to occur in the absence of control. If so, processors must establish controls for glass in their HACCP plans.

Excess detinning represents another potential nonmicrobial hazard for juice. Certain juices are purposely packaged to allow some detinning of the can in order to protect the color quality of the product. However, detinning can be accelerated by unusually high nitrate content in the product or by elevated temperatures during storage or shipping (Refs. 26). Excessive detinning has resulted in consumer illness (Refs. 26 and 27). Thus, processors of juice products that employ detinning as a means of color protection must determine whether it is necessary to establish specific control measures, *i.e.*, a CCP, because excessive detinning is reasonably likely to occur.

Potential hazards may also be caused by the nature of incoming materials. Patulin in apple juice products is one such example. Patulin is a mycotoxin produced by several species of mold that can grow on apples, particularly if bruised or otherwise damaged. A compilation of data from three surveys showed that 19 percent of samples of apple juice contained levels of patulin in excess of 50 µg/L (Ref. 23). FDA has recently issued guidance describing 50 parts per billion (ppb) as a recommended level for patulin (Refs. 19 and 24). For apple juice processors, patulin may represent a hazard that is reasonably likely to occur when juice is made from bruised or damaged fruit, as even moderate bruising can result in mold growth on apples. Moreover, patulin may be a chronic potential hazard and therefore particular attention must be given to the frequency of occurrence. Therefore, a prudent processor must determine whether the frequency of occurrence of this potential hazard in juice is unacceptable without controls. If patulin is reasonably likely to occur at unacceptably high levels, processors must include it as a hazard in their HACCP plans. Patulin is not the sole mycotoxin that may be a hazard in juice. There is evidence that other mycotoxins, such as ochratoxin in grapes and *Alternaria* toxins in fruit and vegetable products (Ref. 28), may be emerging public health problems in juices and at least warrant monitoring of future developments.

Lead contamination has also been associated with juices. In 1996, infant apple prune and prune juices were recalled for unacceptable levels of lead (Refs. 29 and 30). More recently, unacceptable levels of lead have been found in babyfood containing carrots and in carrots in frozen mixed vegetables as a result of lead contamination in the soil (Refs. 31 and 32). Juice made from produce with high lead levels will also be high in lead. A German survey of lead in foods found that 12 percent of fruit juices contained elevated levels of lead and over 5 percent of fruits had elevated levels of lead (Ref. 33). It is well recognized that lead has no known "no-effect level" and consumption of lead-contaminated food is a recognized health problem, particularly for children in their developmental stages. Responsible processors should exercise control to ensure that their juice products do not contain lead at harmful levels. Again, HACCP provides both the necessary control and flexibility to address the problem of lead contamination. If a processor is importing juice from a geographic region known to have a problem with lead contamination in foods, that processor should identify lead as a hazard in their HACCP plan. However, if a juice processor determines through its hazard analysis that, given their source, incoming materials are not reasonably likely to be contaminated with lead, that processor would not need to identify lead as a hazard in its HACCP plan. Importantly, processors who are currently implementing HACCP to address microbial hazards only already have the infrastructure in place to analyze their processing system and can then determine if there are chemical or physical hazards that are reasonably likely to occur. Therefore, with minimal effort, these processors can readily expand the scope of their HACCP system to include consideration of all potential hazards.

Based upon the foregoing, the agency concludes that chemical and physical hazards, as well as pathogens, may pose public health risks in juice products. These hazards, when they are reasonably likely to occur, require specific preventive controls. HACCP is the most appropriate system to control both microbial and nonmicrobial hazards that are reasonably likely to occur in juice products.

(Comment 16) Several comments suggested that quality assurance systems devised specifically for juices would be appropriate alternatives to mandatory HACCP with a performance standard. The comments contended that the quality assurance systems developed by and for the citrus industry in conjunction with the University of Florida (Ref. 34) are adequate to ensure the safety of citrus juices and that the Apple Hill Quality Assurance Program (Ref. 35) is adequate to ensure the safety of apple juice. Some comments asserted that these programs are just as effective as HACCP, while being less expensive to implement.

FDA encourages the efforts by industry, universities, State and local government agencies, and others to develop programs to ensure the safety and quality of the food supply and is aware of several such programs. The agency has reviewed the quality assurance programs mentioned by the comments and finds that the HACCP system in part 120 provides a greater level of public health assurance. If a processor can implement a quality assurance program that also meets the requirements of part 120, then FDA does not object to the processor using that program for its HACCP system. However, quality and safety are not necessarily synonymous. Quality programs focus on the combination of attributes or characteristics of a product that have significance in determining the degree of acceptability of that product by consumers. Safety programs focus on hazards and public health assurance. Quality assurance systems may not address all public health

hazards just as safety programs may not address all quality issues.

(Comment 17) Several comments requested that FDA exempt from the HACCP regulation processors who pasteurize their product, make shelf-stable product, or meet the 5-log performance standard because the aim of the rule should be pathogen control. The comments said that HACCP is regulatory overkill and it is unfair to impose HACCP on the 98 percent who pasteurize in order to control the real risk from the 2 percent who do not. The comments noted that illness outbreak evidence only supports the need for interventions to control pathogens in unpasteurized juice because there have been no reported outbreaks of illness from consumption of pasteurized juice.

The agency agrees that, when used with appropriate times and temperatures, thermal pasteurization [3] is a proven and effective method for controlling pathogens. However, the effectiveness of pasteurization is dependent on implementation of an integrated system that validates and verifies the efficacy of the pasteurization process. It is likely that processors who make concentrated, shelf-stable, or pasteurized juices have already incorporated HACCP principles, aimed at control of pathogens, into their processing operations (Ref. 36). Processors already attaining the 5-log reduction performance standard are likely to have established process parameters (*i.e.*, critical limits), are monitoring the process, and are keeping records of their monitoring. Therefore, it should require minimal effort for processors that make concentrated, shelf-stable, or pasteurized juices to satisfy the requirements of part 120 relating to pathogen control. Moreover, as discussed in section L of this document "Process Controls," in recognition of the effectiveness of thermal treatments for pathogen control, FDA is providing in part 120 an alternative method for processors making shelf-stable juices or certain juice concentrates to comply with the 5-log reduction in the pertinent pathogen. The agency believes that the alternative method is reasonable because the processes for shelf-stable juices and concentrates are so rigorous that they exceed the minimum requirements for control of microbiological hazards. A copy of the thermal process in a processor's hazard analysis will provide evidence that the process is adequate.

Importantly, pathogen control is not the only problem with juice safety. As discussed in the juice HACCP proposal (63 FR 20450 at 20451) (Ref. 2) and in the response to comment 15, there are also established chemical and physical risks with juice. A juice product can only be considered safe if all hazards (*i.e.*, microbial, chemical, and physical) are considered and, if these hazards are reasonably likely to occur, are controlled. Therefore, FDA concludes that processors of thermally processed juice must comply completely with this HACCP regulation, but can do so with minimal added effort.

(Comment 18) Some comments contended that the HACCP proposal goes way beyond establishing necessary measures to ensure juice safety and is neither reasonable nor economically feasible for an industry characterized by small producers, family businesses, seasonal production, and very little prior experience in food safety management. Comments also noted that there is a low level of compliance with seafood HACCP among small producers and the success of juice HACCP will depend upon small processors complying with costly regulations. Conversely, several comments argued that HACCP is the appropriate food safety system for small producers because it can be implemented without being overly burdensome and forcing them out of business.

The flexibility of HACCP allows the processor to control hazards identified in the hazard analysis in a manner that best fits an individual operation, large or small. In addition, if small producers actually have very little prior experience or knowledge in food safety management, as some comments asserted, then HACCP training and consultation are very much needed by this group and will provide specific food safety goals customized to their individual operations.

Thus, features of the agency's regulatory strategy will accommodate small processors. First, FDA intends to provide a juice HACCP hazards and controls guidance that will assist processors. Second, this final rule has a staggered compliance schedule (§ 120.1(b)(1) and (b)(2)), which provides small and very small juice processors additional time to implement fully the final rule.

The agency's HACCP strategy for the seafood industry, which is dominated by small processors, has been to acknowledge that the implementation of HACCP can be an educational process, especially with regard to science-based analysis, and thus to allow for the progression in mastering the HACCP system that accompanies that process. The progress in implementing HACCP systems that the seafood industry is making suggests that other segments of the food industry, including those populated by small businesses, can also benefit from a HACCP program, even if complete understanding of what constitutes full implementation of a HACCP system is not immediate.

(Comment 19) Several comments stated that HACCP presents an undue burden to the pasteurized juice industry with no consumer benefits. The comments stated that the chemical hazards cited by FDA are not reasonably likely to occur and that there has never been a foodborne illness outbreak associated with pasteurized juice.

The agency does not agree. The preamble to the proposed rule described incidents of illness associated with chemical contaminants in juice (63 FR 20450 at 20451) (Ref. 2). Chemical hazards can occur in juice regardless of pasteurization. Moreover, for some juices, the risk of chemical contamination can be high, depending on the quality of the incoming produce and the chosen processing steps. In fact, in two recent incidents, juice was recalled by the processor in one case due to the presence of dairy and egg allergens (Refs. 37 and 38), and in the other, due to the presence of cleaning solution (Refs. 39, 40, and 41). As discussed earlier in comment 15, the risk of patulin contamination in apple juice is high if the processor uses bruised apples.

The agency does not agree that HACCP for the pasteurized juice industry does not convey benefits to consumers. While the classic definition of pasteurization is a heat-treatment to destroy pathogens, the agency has no assurance that all juice processors who believe they are pasteurizing their products actually have all the controls in place to assure that every particle of the juice is receiving sufficient heat to destroy pathogens. Moreover, pasteurization alone does not assure the safety of juice products. Proper handling of the product after pasteurization is required to prevent post-process contamination. A HACCP system based on CGMP's provides assurance to the processor, as well as to the agency and the consumer, that pasteurized products are safe.

The agency is required, by Executive Order and law, to consider both the costs and benefits to consumers and industry. This analysis can be found in the PRIA, and the Regulatory Flexibility

[3] FDA has not defined what pasteurization means in terms of juice and juice products because of the unique characteristics of the many various types of juice and juice products. The scientific literature provides data on adequate pasteurization times and temperatures. Prudent processors using pasteurization rely on this research data for their particular types of juices

Analysis in sections V and VI of this final rule. Based on FDA's analysis, the benefits (*i.e.*, prevention of illness) of this final rule outweigh the costs to industry.

A few comments expressed concern that HACCP regulations may be enforced at the expense of CGMP's.

The agency does not agree with the comments. In fact, FDA expects that the opposite will be true. A HACCP system cannot be operating properly if a processor is not following CGMP's because CGMP's provide the foundation for an adequate and appropriate HACCP system. Therefore, to evaluate the effectiveness of a HACCP system, processors and agency inspectors must also evaluate processors' adherence to CGMP's.

(Comment 20) One comment stated that HACCP as set forth in the proposal places the responsibility for product safety on the government rather than the processor.

FDA does not agree with this comment. Each juice processor is responsible for developing a system of preventive controls by adapting the HACCP principles in new part 120 to its specific operation and needs. Under HACCP, the manufacturer is responsible for knowing and understanding its manufacturing process, identifying points where contamination can occur, and implementing control measures in order to produce safe food. To accomplish this, the processor must: (1) Have an individual who is trained in HACCP conduct a hazard analysis, determine where controls are needed, and validate the adequacy of any HACCP plan that is developed; (2) put those controls in place and verify that they are working through monitoring and recordkeeping; and (3) revalidate the HACCP plan at least annually or any time there is a significant change in the process or whenever scientific information demonstrates a new risk that processors have not previously considered in their hazard analysis. FDA's responsibility is to conduct oversight to ensure that HACCP is properly implemented and is effective.

(Comment 21) Several comments stated that HACCP's cost is not justified because most foodborne illness occurs as a result of problems that originate after juice leaves the processor and HACCP will not remedy these problems. One comment cited a source that estimated that food manufacturers are involved in less than 10 percent of foodborne disease outbreaks of known origin (Ref. 42).

FDA maintains that all steps in juice production and handling are potential points of contamination in the absence of adequate controls, not just post-process handling. Processors must consider prevention of post-process contamination to the extent feasible. For example, post-process piping must prevent contamination from occurring prior to packaging. HACCP systems are implemented to assure the safety of food when it leaves the processor's control and under normal handling conditions after that. The agency points out that the CAST report cited by the comment includes all foods (not just juice) and all food sources (processors, food service, institutions) and is limited to microbial contamination of foods. The majority of juice outbreaks have not been caused by post-process contamination but rather by contaminated incoming product or contamination during processing (Ref. 43). Thus, the performance standard (5-log reduction in pathogen level) established by this rulemaking is set to ensure that the final product is not contaminated with illness-causing bacteria that may have been present on incoming fruit. In addition, processors must use CGMP's, SSOP's, and HACCP to ensure that product is not contaminated with pathogens while in the processing facility.

(Comment 22) Several comments stated that hazards in juice are adequately dealt with under State laws (*i.e.*, Connecticut, Florida, Illinois, Maryland, Massachusetts, Michigan, New Jersey, New Hampshire, Wisconsin).

The agency applauds State efforts to ensure the safety of juice produced and sold in their States. However, while there may be some State laws that govern the manufacture of juices, these laws are generally not as comprehensive as this HACCP rule. In addition, not all juice producing States have applicable State laws. This HACCP final rule provides a uniform minimum level of public health protection across the country for juices. FDA believes that this final rule will enhance State efforts and help extend the food safety efforts of some States to all States.

C. Significance of Illness Data

The preamble to the proposed regulation described occurrences of juice-related foodborne illness in the United States. It is well recognized that foodborne illnesses are significantly underreported to public health authorities (Ref. 44). Consequently, precise data on the numbers and causes of foodborne illness do not exist. The primary purpose of these regulations is to ensure that juice is safe through the use of preventive controls that are systematically and routinely applied in juice processing, and applied in a way that can be verified as effective by company management as well as regulatory authorities.

(Comment 23) Many comments questioned the validity of FDA's risk assessment on juice. They stated that it was not scientific and sound, not probabilistic, didn't include pasteurized juice, and contains inaccuracies. However, comments did not specifically identify the inaccuracies.

FDA maintains that its "Preliminary Investigation into the Morbidity and Mortality Associated with the Consumption of Fruit and Vegetable Juices" is sound. As outlined in the juice labeling final rule (63 FR 37030 at 37031) (Ref. 5), the agency performed a detailed evaluation of the potential hazards posed by untreated juices. This evaluation is part of the record of the HACCP proposal and was included as an appendix to the PRIA (63 FR 24292; May 1, 1998) (Ref. 6). The evaluation was based on available scientific information, included pasteurized juice, and examined both heat-treatable microbial hazards and non-heat-treatable hazards. Non-heat-treatable hazards are discussed in section VII and the evidence is summarized in table 7 of FDA's Investigation. The conclusion that the most significant juice-borne hazards are associated with non-heat-treated juice was based on this investigation.

(Comment 24) One comment stated that all outbreaks in cider have been traced to using dropped apples or unsanitary processing conditions and that eliminating these circumstances will stop outbreaks in cider.

FDA disagrees with the comment because the causes of cider-related outbreaks are not limited to using drops or processing in an insanitary facility. In fact, from a structural standpoint, apples are susceptible to contamination because they have an open blossom end, and thus, the interior of the fruit can be contaminated while the exterior appears clean and blemish free (Ref. 45). This potential for contamination is confirmed by data that show that cider, even when it is made from tree-picked fruit and processed under CGMP's, can contain pathogens and provide an environment conducive to the survival of pathogens of public health significance (Ref. 13).

(Comment 25) Several comments maintained that the risk from juice is low and does not warrant a HACCP regulation.

The agency does not agree with the comments. There are documented cases of lifethreatening foodborne illness associated with the consumption of various juice products contaminated with pathogens such as *E. coli* O157:H7,

Salmonella species, *Cryptosporidium*, and *Vibrio cholerae*. Some of the illnesses associated with juices have been very severe (*e.g.*, cases of long-term reactive arthritis and severe chronic illness) (Ref. 2). In one case, consumption of contaminated juice resulted in the death of a child and in another case, consumption of contaminated juice contributed to the death of an elderly man. These reported outbreaks likely represent only a fraction of the outbreaks and sporadic cases that actually occur (Ref. 44).

Chemical and physical hazards have also been associated with juices. Examples of these hazards were included in the proposal (63 FR 20450 at 20451) (Ref 2) and are discussed in detail in the response to comment 15.

The evidence demonstrates that hazards can be present in juice. The comments did not provide the agency with additional data that either contradict FDA's hazard evaluation (Ref. 6) or that can be used to reevaluate the health risks associated with consumption of juice products. Therefore, FDA believes that the public health risk associated with consumption of juices is sufficiently high to justify mandating use of HACCP systems.

(Comment 26) Many comments argued that HACCP is no longer necessary for juice because of the safety improvements made by the juice industry since the 1996 outbreak of *E. coli* O157:H7 in apple juice. They stated that these improvements are evidenced by the fact that there has not been an outbreak associated with juice since 1997.

FDA disagrees with the comments. There have been documented outbreaks of juice-associated foodborne illness since 1997. The agency acknowledges the recent steps taken by the industry to address microbial contamination of juice. Nevertheless, while there were no reported outbreaks attributed to juice in the United States in 1997 and 1998, there were several outbreaks in 1999 and 2000. These outbreaks are discussed below.

In early 1999 in south Florida, there were 16 reported cases from *Salmonella typhi* linked to the consumption of frozen mamey, a product often used to make juice beverages (Ref. 46).

During June 1999, there was an outbreak of *Salmonella* serotype Muenchen infection associated with consumption of unpasteurized orange juice (Ref. 47). As of April 2000, a total of 423 cases, including one that contributed to a death, from S. Muenchen infection had been reported. Nine additional *Salmonella* serotypes were identified from orange juice collected from the implicated firm.

In October 1999, there was an outbreak of *E. coli* O157:H7 in commercially-processed unpasteurized apple cider in Oklahoma with 9 illnesses (7 children) and 6 hospitalizations (4 cases of hemolytic uremic syndrome (HUS)) (Ref. 48).

While no illnesses were reported in October 1998, the State of Florida found *Salmonella* Manhattan in an unpasteurized juice blend containing strawberry, apple, and papaya juice (Ref. 49).

In November 1999, the same firm involved in the June 1999 outbreak initiated and subsequently expanded a recall because their routine testing found *Salmonella* in samples of unpasteurized orange juice (Ref. 50). The product had been distributed to restaurants and other food service establishments in eight U.S. States and one Canadian Province and to one retail store in Oregon. No known illnesses were associated with this incident.

In April 2000, there was an outbreak of *Salmonella* Enteritidis associated with unpasteurized orange juice (Ref. 51). As of May 2000, 143 cases traced to this orange juice had been identified in Arizona, California, Colorado, Minnesota, Nevada, Washington, and Wyoming.

Also in April 2000, 24 people who attended a conference in Atlanta, Georgia, were reported ill with viral gastroenteritis (Ref. 52). Fresh-squeezed unpasteurized fruit smoothies were implicated in this outbreak. CDC detected Norwalk-like virus in three patient stools.

Thus, the potential for juice-related illness still exists, although the number of illness outbreaks linked to juice may vary from year to year. In addition, the agency has no information indicating that all members of the juice industry have implemented adequate safety improvements to address the potential for microbial contamination and other potential hazards in their products. The fact that outbreaks continue to occur is evidence to the contrary.

(Comment 27) One comment asserted that most problems associated with citrus juices were a result of insanitary processing conditions at small or very small businesses or contamination by asymptomatic food handlers, and HACCP would not prevent problems in either situation.

The agency disagrees with this comment. FDA often finds in their investigations into outbreaks that the exact cause of the outbreak is unknown The agency may find various possible causes that include those mentioned by the comment. However, as discussed throughout this preamble, insanitary conditions and workers' health are not the only source of food hazards in juice. For example, if juice is made from contaminated fruit and the 5-log reduction is not accomplished, an outbreak could occur. HACCP systems do provide greater assurance than CGMP's and SSOP's alone that juice is safe. HACCP recordkeeping provisions allow processors and regulators to detect process deviations and stop distribution of or recall product before it results in an outbreak.

(Comment 28) Several comments stated that the rules should cover apple products only, asserting this is where problems have occurred.

The agency disagrees that only apple juice should be covered by part 120, and all other juices should be exempt. There have been illness outbreaks from other types of juice, *e.g.*, orange juice. Some of these were cited in the proposal (63 FR 20450) (Ref. 2). As discussed in comment 27, additional outbreaks since publication of the proposal have occurred. Therefore, FDA concludes that because there are documented foodborne illness risks associated with juices other than apple juice, all types of juice must be covered under part 120.

(Comment 29) Many comments argued that juice regulations should not be more stringent than regulations for other foods that are more hazardous, such as seafood or meat and poultry. Many comments noted that seafood HACCP has no performance standard but is a much higher risk food than juice.

The agency disagrees that juice is being regulated more stringently than warranted. HACCP for juice mirrors FDA's HACCP regulations for seafood and USDA's regulations for meat and poultry. In contrast to most seafood and meat and poultry, juice is generally consumed as sold. The record of this proceeding demonstrates that microbial contamination of juice is a substantial public health risk and that a performance standard is achievable as a practical matter. Thus, to ensure the safety of juice products, FDA is establishing a mandatory HACCP program that includes a performance standard to prevent, reduce, or eliminate levels of pathogens known to cause foodborne illness. The performance standard ensures that controls within the HACCP system are working effectively to reduce the risk of illness and that the final product is safe.

(Comment 30) One comment maintained that the physical hazards related to juice are a result of metal cans

and glass, both of which are not used by the fresh juice industry.

FDA recognizes that juices that are minimally processed usually are packaged in plastic to provide for expansion of the product. Whether or not packaging materials are included in a processor's HACCP plan will be determined in the processor's hazard analysis. If the hazard analysis shows that a particular operation has no physical hazards, such as metal or glass, that are reasonably likely to occur, no control measures are required for such hazards. Even if there are no physical hazards in fresh juice that require controls, the risk of microbial contamination of fresh juice is well-documented and a HACCP approach is needed to address these risks.

(Comment 31) One comment stated that the *Bacillus cereus* incident cited by FDA is not significant and any final rule should clearly state that sporeformers are not a problem that needs to be considered in a treatment system for juice.

The agency has considered the issues surrounding hazards from spore forming bacteria. Regulations in parts 113 and 114 (21 CFR parts 113 and 114) already address the hazard from *Clostridium botulinum* in low acid canned foods and acidified foods. Spore forming bacteria have not been associated with public health problems in juice that has been properly handled (*e.g.*, refrigerated) after leaving the processing plant. Therefore, FDA does not anticipate that processors' hazard analyses will establish that spore forming bacteria are a hazard that is reasonably likely to occur.

D. Comparison of the Proposal and This Final Regulation

The comments received generated some clarifications of and changes in provisions of the proposed regulation. These are discussed in detail in the comments noted after each item. Among the most significant clarifications and changes are the following:

- Clarification that the regulation covers intrastate, as well as interstate juice (discussed in comments 33 and 74)
- Adoption of the most recent NACMCF definition of "food hazard" (comment 39)
- Elimination of the proposed exemption from the regulation for retail establishments that produce juice on their premises and sell 40,000 or less gallons of juice per year (comment 47)
- Addition of a definition of "retail establishment" (comment 48)
- Clarification of how a hazard analysis is conducted (comments 63 to 70)
- Clarification of application of the 5-log pathogen reduction performance standard (comments 115 and 131 to 139)
- Creation of an exemption for shelf-stable juice processors and concentrated juice processors from the requirement for a pathogen reduction critical control point, under specific conditions (comment 140)
- Establishment of a process verification sampling and testing procedure for citrus juices that use surface treatment as part of the 5-log pathogen reduction process (comment 142 to 143)

III. The Final Regulation

A. Applicability

The agency proposed in § 120.1(a) that any juice sold as such or used as an ingredient in beverages be processed in accordance with the requirements of part 120 (63 FR 20450 at 20462) (Ref. 2). As proposed, juice is the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or puree.

(Comment 32) One comment requested that FDA define juice as the aqueous liquid expressed or otherwise extracted from food and that this definition should be synonymous with juice definitions in other regulations, *i.e.*, food standards. One comment noted that food products (*e.g.*, fruit cocktail) other than beverages contain fruit juice.

FDA advises that the purpose of § 120.1(a) is to define the scope of what is covered under part 120 rather than to provide a general definition for the term "juice." Part 120 only covers products sold as juice or used as an ingredient in beverages. The agency recognizes that products other than beverages, *e.g.*, canned fruit cocktail, may contain fruit or vegetable juice. However, the foodborne illness outbreaks prompting the juice HACCP proposal were associated with juices and juice products that were beverages rather than juice ingredients contained in non-beverage products. Therefore, FDA is not defining "juice" in the general sense requested by the comment.

(Comment 33) Several comments requested that FDA clarify whether the juice HACCP regulation covers only interstate commerce.

FDA intends that this final rule cover both "interstate juice" (*i.e.*, juice that is shipped in interstate commerce or that is made using one or more components that were shipped in interstate commerce) and "intrastate juice" (*i.e.*, juice that is made entirely from components grown within a single State and then sold to the ultimate consumer within the same State).

As noted in the proposal, FDA is relying upon both its authority under the act, 21 U.S.C. 321 *et seq.*, and the Public Health Service Act, 42 U.S.C. 241, 242l, 264. FDA's authority to regulate "interstate juice" is discussed in detail below in comment 74. Under section 361 of the Public Health Service Act (42 U.S.C. 264), the Surgeon General is authorized to issue and enforce regulations to prevent the introduction, transmission, or spread of communicable diseases from one State to another State. (This authority has been delegated to the Commissioner of Food and Drugs, 5 CFR 5.10(a)(4).) Activities that are wholly intrastate in character, such as the production and final sale to consumers of a regulated article within one State, are subject to regulation under section 361 of the PHS Act *State of Louisiana* v. *Mathews*, 427 F. Supp. 174, 176 (E.D. La. 1977). The record in this rulemaking amply demonstrates that juice can function as a vehicle for transmitting foodborne illness caused by pathogens such as *Salmonella* and *E. coli* O157:H7. Similarly, the record (Ref. 53) demonstrates that consumers (particularly out-of-State tourists and other travelers) are likely to purchase and/or consume "intrastate" juice. These consumers subsequently take the juice back to their home State where the juice is consumed or carry a communicable disease back to their home State, thereby creating the risk that foodborne illness may occur in the home State as a result of such consumption.

The agency believes that its intent to regulate both "interstate" and "intrastate" juice was evident from § 120.1(a) of the proposal, which stated that the requirements of part 120 would apply to "any juice" without qualification as to its "interstate" or "intrastate" character. However, to clarify further the products to which this final rule applies, FDA is adding a sentence to § 120.1(a) as follows: "The requirements of this part shall apply to any juice regardless of whether the juice, or any of its ingredients, is or has been shipped in interstate commerce (as defined in section 201(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321(b))."

(Comment 34) Some comments requested that FDA exempt citrus juices from the HACCP regulation because these juices contain organic acids that stop microbial growth, the pH of citrus juices is too low for pathogen growth, and peel oil contains an antimicrobial agent. One comment included data

indicating that *Listeria* and *E. coli* O157:H7 cannot survive in lemon and lime juices under normal storage conditions and requested that these two juices be exempted from the HACCP rule.

The agency disagrees that citrus juices should be exempt from the requirements of part 120. Although the organic acids, pH, and peel oil in citrus juice may inhibit (*i.e.*, prevent or slow down) the growth of pathogens, such organisms can still be present in citrus juice and may cause illness if consumed. Fruits and vegetables differ in their inherent chemical composition; even within varieties of particular fruits or vegetables, there can be some variation in composition depending on growing conditions. However, the comments provided no data to show how the chemical composition of a citrus juice (pH or antimicrobial compounds in peel oil) will ensure the safety of fresh citrus juice. In fact, because the amount of peel oil in juice will vary from process to process, the agency disagrees that the antimicrobial effects of citrus peel oil can adequately control pathogens in juice. Similarly, the organic acid in citrus juice (*i.e.*, citric acid) has not been shown to provide any additional protection against pathogen contamination and survival compared to the acid found in apple juice (Refs. 54, 55, and 56).

A 1997 study of *E. coli* O157:H7 behavior in apple juice and orange juice, particularly under refrigerated conditions, demonstrated that even in the relatively acidic environment of these juices, this organism can survive (Ref. 57). In the study, juice was inoculated with *E. coli* O157:H7. After a 24-day period at refrigeration temperatures, there was only a small decline in numbers of *E. coli* O157:H7. The fact that *E. coli* O157:H7 can survive in orange juice and that human illnesses from other pathogens, such as *S. Muenchen* and other *Salmonella* species, have been traced to orange juice demonstrates that, if contaminated, orange juice has the potential to cause human illness.

Lemon and lime juices are more acidic than other types of citrus juice. The strong acidity of these juices does have an antimicrobial effect as the comment's data demonstrated However, the resistance of oocysts to the strong acidity of these juices is not known. In addition, there can be differences in acidity between varieties of lemons and limes, and thus, differences in their inherent antimicrobial effects. These juices may be diluted and sweetened to make them palatable as beverages, thus changing antimicrobial parameters. In addition, there may be chemical and physical hazards that are reasonably likely to occur in these types of juices that pH and acids cannot control. Therefore, FDA concludes that the chemical composition of lemon and lime juices does not justify exempting these juices from this rule. If processors can demonstrate that the inherent antimicrobial qualities of a juice are adequate to accomplish the 5-log reduction in the pertinent pathogen under refrigerated conditions (or freezing conditions, if the product is frozen) prior to the product leaving the processing facility, then the antimicrobial parameters, along with the necessary time to accomplish the 5-log reduction, could constitute CCP's. FDA notes, however, that under the final rule, processors must establish critical limits and monitor each of the CCP's as part of their HACCP systems.

(Comment 35) Some comments maintained that there is less inherent risk from citrus juices because citrus processing limits contact time of peel and juice. The comments included data from citrus processors that separate the peel from the juice with only a small fraction of peel contacting the juice.

The agency disagrees that there is less risk from citrus juices such that these juices should not be subject to part 120. The significance of peel/juice contact as a source of pathogens in the juice depends on several factors, including the microbial load on the peel and the amount of contact of the peel with the juice. If the small fraction of peel, as described by the comments, is contaminated and comes into contact with the juice, that contact is significant. As discussed in the proposed rule (63 FR 20450) (Ref. 2) and also in the response to comment 26, there have been outbreaks of food borne illness associated with orange juice.

(Comment 36) A few comments requested that FDA exempt apple cider from the HACCP regulation because the agency found no pathogen contamination in the 1997 cider survey, which, according to the comment, indicates that there is no real risk from pathogens in cider.

FDA's 1997 survey involved inspection of fresh unpasteurized apple cider operations at 237 processors in 32 States (Ref. 45) during which the agency collected samples at various processing steps. These samples were analyzed for *E. coli* O157:H7, *Salmonella*, *Staphylococcus aureus*, fecal coliforms, and generic *E. coli*. Although the survey did not detect any pathogens in finished juice products, one firm's apples tested positive for *Salmonella*, demonstrating that pathogens can occur on incoming apples (The analytical method used for *Salmonella* has since been improved to better detect low levels of this pathogen in acidic foods, such as apple juice.) Results also showed that samples of wash water from several firms tested positive for generic *E. coli* and fecal coliforms; overall, generic *E. coli* was found in 15 percent of the finished product samples. The presence of fecal coliforms and generic *E. coli* are widely recognized as indicators of fecal contamination (Ref. 58). Further, the survey concluded that it is likely that any microbial hazards that are introduced at the beginning of processing will be carried through to the finished product; no microbial reduction will occur during the process (Ref. 45).

The agency disagrees that these results indicate there is no real risk from pathogens in cider. Contrary to the comments' contention, the cider survey results affirm that risk factors such as fecal coliforms, an indicator of the possible presence of pathogens, as well as pathogenic bacteria, such as *Salmonella*, are present in cider processing operations and could give rise to microbiological safety hazards in finished cider products.

Finally, illness outbreaks associated with apple cider continue to occur. In particular, in October 1999 in Oklahoma, there was an outbreak related to *E. coli* O157:H7 in a commercially produced, unpasteurized apple cider, that resulted in nine reported illnesses. The agency, therefore, is not granting the requested exemption.

(Comment 37) Several comments requested that FDA clarify whether concentrates are covered under the rule.

The agency advises that under the final rule, a juice concentrate satisfies the definition of "juice" in § 120.1, and thus, producers of concentrates are required to comply with part 120.

(Comment 38) One comment requested that FDA clarify whether processors of beverages that include juice as an ingredient but do not produce the juice itself are covered under the juice HACCP regulation. One comment stated that dairies using concentrates that are processed to meet the 5-log requirement or untreated juices that are further pasteurized should not be subject to the HACCP regulation.

The agency advises that any juice processing activity, including juice ingredient processing, must comply with the provisions of part 120. Dairies making juice, regardless of whether they use concentrates, must comply with part

120. However, dairies producing a non-juice beverage that contains a juice ingredient (*e.g.*, a dairy-based beverage containing orange juice) are not required to comply with part 120 in terms of the process for producing that non-juice beverage. Processors of juice used as a beverage ingredient must comply with the provisions of part 120.

B. Definitions

1. Food Hazard

FDA proposed in § 120.3(e) (finalized as § 120.3(g)) that "food hazard" means any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

(Comment 39) One comment requested that FDA adopt the most recent NACMCF definition of a food hazard to clarify the mechanism by which a hazard analysis is conducted.

The agency agrees with this comment. The NACMCF currently defines "hazard" as a "biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control" (Ref. 17). The definition differs from, but is not inconsistent with, the definitions for food hazards used in the seafood HACCP and meat and poultry HACCP regulations. Adopting the most recent NACMCF recommendations to the extent feasible will allow the HACCP regulation to remain current with the science of HACCP.

In the first step of a hazard analysis, processors must identify all the hazards that could potentially occur in the juice. Potential hazards are those microbial, chemical, and physical agents that are reasonably likely to cause illness or injury regardless of the likelihood of their occurrence. FDA intends to publish a juice HACCP hazards and controls guidance to assist processors in this step of the hazard analysis.

Second, processors must determine whether the potential hazards identified are "reasonably likely to occur" in their particular process. Under § 120.7(b), a hazard is "reasonably likely to occur" if a prudent processor would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that, in the absence of those controls, the food hazard will occur in the particular type of product being processed.

In the NACMCF's view, if a hazard has a severe, acute public health impact (*e.g.*, illness caused by a pathogen, injury caused by ingestion of glass), that hazard presents a significant risk even at an extremely low frequency of occurrence and must be appropriately identified as a hazard that is "reasonably likely to occur" (Ref. 17). FDA concurs in this view. On the other hand, chronic hazards would need to occur at a higher frequency to be identified as a hazard that is "reasonably likely to occur." In the case of chronic hazards, it must be understood that the illness or injury need not be caused by any specific occurrence of the hazard but may occur with exposure to the hazard over time. Each hazard identified in the hazard analysis as "reasonably likely to occur" requires the identification of at least one CCP, the critical step or steps in the process that must be controlled to prevent, reduce to acceptable levels, or eliminate the hazard.

Because hazards can be either acute or chronic (*i.e.*, having short-term or long-term effects, respectively) and the purpose of HACCP is to focus on public health hazards that are "reasonably likely to occur," FDA finds that the NACMCF definition better describes what must be considered in a hazard analysis. Therefore, the agency is modifying § 120.3(g) to state that a "food hazard" means any biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

2. Processing

The agency proposed in § 120.3(h)(1) (finalized as § 120.3(j)(1)) to define "processing" as activities that are directly related to the production of juice products. However, for purposes of proposed part 120, certain activities were proposed to be exempted by § 120.3(h)(2) (finalized as § 120.3(j)(2)). These are: (1) Harvesting, picking, or transporting raw agricultural ingredients of juice products, without otherwise engaging in processing; (2) the operation of a retail establishment; and (3) the operation of a retail establishment that is a very small business and that makes juice on its premises, provided that the establishment's total sales of juice and juice products do not exceed 40,000 gallons per year, and that sells the juice (a) directly to consumers or (b) directly to consumers and other retail establishments.

a. Harvesting, Picking, and Transporting Raw Agricultural Products.

(Comment 40) Several comments objected to the definition of processing in proposed § 120.3(h)(2)(i) (finalized as 120.3(j)(2)(i)) excluding harvesting, picking, and transporting raw agricultural ingredients of juice products because this will leave a big gap in the farm to table system and contamination is very likely to occur in this gap. One comment advocated mandatory HACCP that either begins at the farm including harvesting, picking, and transport or includes a "kill step."

The agency has concluded that it would be unduly burdensome to require that harvesting, picking, and transportation be included as part of a processor's HACCP system or to require a kill step. Under HACCP, processors are responsible for evaluating their production system for hazards and establishing CCP's. This includes the quality of incoming raw materials. FDA encourages farmers and processors to evaluate and modify their agricultural practices in accordance with FDA's "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables" (Ref. 59). This guidance document is based upon certain basic principles and practices associated with minimizing microbial food safety hazards from the field through distribution of fresh fruits and vegetables. Farmers should take all steps to ensure their products are safe for the intended food use, but safe juice can be produced without these activities at the farm level coming under the processor's HACCP system. Processors can control hazards that may be present on incoming produce by: (1) Rejecting produce at receipt that does not meet processor specifications; (2) removing contaminated produce during initial processing; (3) cleaning and sanitizing produce; (4) using, as a minimum standard, the 5-log reduction in the pertinent pathogen as set forth in § 120.24; and (5) using any other effective method.

The agency does not believe it is appropriate to mandate a "kill step" in the absence of HACCP at the farm. It is the processor's decision, based on its hazard analysis whether or not the first CCP in its HACCP system is at the point of receipt of raw materials, to control hazards that may have occurred earlier. The hazard analysis must be based on experience, illness data, scientific reports, or other information that provide a basis to conclude that there is a reasonable possibility that, in the absence of HACCP controls, the food hazard will occur in the particular type of product being processed. The performance standard establishes the minimum level of microbial pathogen reduction the process must be able to provide to produce safe juice and this may be met by a "kill step" or any other appropriate method. The 5-log reduction in the pertinent pathogen is adequate to ensure that the juice is safe when done under a HACCP system with a foundation of CGMP's and SSOP's.

(Comment 41) One comment suggested that the definition of processing should at least mention FDA's "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables" (GAP's).

FDA has considered the comment's suggestion and believes that reference to the GAP's in part 120 would be useful. However, the agency finds that it is more appropriate to discuss the GAP's in terms of the application of part 120. Therefore, FDA is modifying § 120.1(a) to state that raw agricultural ingredients are not subject to the requirements of this part and that processors should apply existing agency guidance to minimize microbial food safety hazards for fresh fruits and vegetables in handling raw agricultural products.

b. Retail.

(Comment 42) Several comments were opposed to excluding retail establishments from the definition of processing in proposed § 120.3(h)(2)(ii) (finalized as § 120.3(j)(2)(ii)). The comments expressed concern because outbreaks associated with products processed in retail establishments will be equally devastating to the industry as a whole. One comment stated that relying on the Food Code and State regulators is inadequate because: (1) The adoption of Food Code provisions is voluntary and varies widely on a State-by-State basis and (2) State regulators do not have the resources to inspect retail establishments on a regular basis.

The agency recognizes that retail is an important segment of the juice industry and that retailers may also mishandle products. FDA is concerned that juice sold at retail be safe. However, retail establishments pose a unique situation for the implementation of HACCP. Retail establishments, in general, deal with a greater variety of products and processes at relatively lower volumes than non-retail producers. For example, cider retailers at farmers' markets will generally sell other products, including fresh produce, as well as apple cider. Therefore, because retail establishments handle lower volumes of a variety of products, HACCP systems at retail are significantly different from HACCP systems in processing plants. Because of the wide variety of products and processes used by retail establishments, the relatively low volumes of juices produced, the normally small area of product distribution, and the large number of retail establishments, FDA has chosen to focus its regulatory resources on manufacturers that produce larger quantities of widely distributed products

Even though retail establishments are not included in this rulemaking, prudent retailers should take steps to ensure the safety of their products. FDA traditionally provides guidance to the retail industry through the Food Code and works with the States to implement Food Code provisions. The States should be aware that the Food Code is responsive to many of the concerns raised in the comment. FDA encourages juice retailers to implement Food Code provisions. Also, FDA provides training and other forms of technical assistance to States and local Governments who inspect retail food establishments through the agency's retail Federal/State cooperative program. The agency will continue to provide this support through the Federal/State cooperative mechanism. FDA recognizes that not all States have adopted the Food Code.

Finally, more than 25 States have adopted the Food Code as law with most other States in the process of adopting the Code. However, retail establishments pose an inspection burden well beyond the capacity of FDA. There are not sufficient resources to adequately inspect the many retail establishments in the United States.

Although retail establishments are not covered in this final rule, they are subject to § 101.17(g), which requires that packaged untreated juice products carry a statement informing consumers that the product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems.

(Comment 43) One comment suggested that, rather than exempting all retail establishments from the definition for processors, only retailers who produce in batches of less than 32 ounces at a time or who sell product in glass containers that can be washed and reused might be exempted because the less fruit and vegetables that go into a batch, the lower the risk.

The agency agrees with the concept that the smaller the batch, the lower the microbial risk. Larger establishments produce larger quantities of juice that are often widely distributed. Retail establishments produce much smaller quantities of juice that are more likely (but not always) consumed locally. Thus, the public health impact of a foodborne illness outbreak associated with larger firms is likely to be greater. However, the special considerations discussed in the response to the previous comment still exist for retail firms, regardless of batch size. Therefore, FDA concludes that it is appropriate that part 120 excludes operators of retail establishments from the definition of processor.

(Comment 44) One comment requested that FDA establish national standards for juice processors in the Food Code if the agency excludes retail establishments from the definition for processing. Conversely, several comments stated that the provisions of the Food Code adequately ensure juice safety at retail. A few comments stated that the guidelines developed by the Fresh Citrus Juice Task Force in combination with Food Code provisions are adequate to ensure the safety of citrus juice without mandatory HACCP for retailers.

FDA agrees with the comments that maintain that the Food Code describes appropriate controls that can be applied to reduce juice hazards at retail. The agency has traditionally relied on the Food Code to provide guidance to retail establishments. As noted in the response to comment 42, FDA will work with the States through its Federal/State mechanism. The agency urges retailers to implement State and industry guidance in their establishments to ensure the safety of juice.

(Comment 45) One comment suggested that all juice, like milk, should be pastuerized and FDA should not permit the sale of untreated juice since raw milk sales are not allowed.

The agency agrees. Under § 120.24(a), processors must include in their HACCP plans control measures that will produce, at a minimum, a 5-log reduction in the pertinent pathogen. Thus, all juice subject to part 120 will be treated to control microorganisms.

(Comment 46) One comment requested information on which processors will not be covered under either the juice labeling rule or the juice HACCP rule and which processors, if any, have a permanent labeling option.

The agency advises that § 101.17(g) requires that any packaged juice in interstate commerce that has not been specifically processed to prevent, reduce, or eliminate the presence of pathogens must bear the warning statement. Under this final rule, a juice retailer as defined in § 120.3(l) is not required to establish a HACCP system; however, any juice produced by that retailer that includes an interstate ingredient or is shipped in interstate commerce must bear the warning label statement. Such a retailer may avoid the labeling requirements by treating its product to achieve a 5-log reduction in the pertinent microorganism.

c. 40,000 gallon exemption.

(Comment 47) Most of the comments on the 40,000 gallon exemption from both large and small processors requested that FDA withdraw the exemption in proposed § 120.3(h)(2)(iii)

(the definition of "processing"). The comments stated that small processors are just as likely to produce contaminated juice as larger processors and that company size should not dictate compliance with regulations when public safety is at stake. The comments also noted that this exemption does not maximize public health protection.

The comments have persuaded the agency to exclude from this final rule the exemption proposed for very small retail businesses who sell less than 40,000 gallons of juice annually either to consumers directly or to other retailers. FDA agrees that company size should not dictate compliance with food safety rules. The agency also agrees with comments that stated that this exemption does not protect the public health. Although large processing firms can be responsible for more widespread outbreaks than the firms in the proposed exemption because of their broader product distribution, those smaller businesses can make juice that may cause an outbreak. Further, other regulations addressing public health concerns (*e.g.*, seafood HACCP in part 123 (21 CFR part 123) mandatory pasteurization of milk and milk products in 21 CFR 1240.61) do not contain such exemptions. Therefore, the agency is removing the exemption from this final rule. FDA notes that those producers who would have been covered by the 40,000 gallon exemption and who are strictly engaged in retail sales would not be required to comply with this final rule consistent with § 120.3(j)(2)(ii). Juice produced by these retailers would be required to bear the label warning statement as described in the response to comment 46.

3. Retail Establishment

(Comment 48) Several comments requested that FDA define "retail establishment" for clarity. One comment requested that FDA revise proposed § 120.3(h) so that retailers who sell to other retailers are covered by the definition for processors.

FDA agrees with the comment that recommended establishing a definition of "retail establishment." The FDA Food Code has a definition of " food establishment", which, given the purpose and scope of the Food Code, is essentially a definition of a retail establishment. In establishing a definition for "retail establishment" in this final rule, FDA is relying on this Food Code definition. The Food Code definition of " food establishment" has been in existence for many years, and is recognized by the States. The Food Code definition includes establishments in which juice is produced and sold directly to consumers in stores, from roadside stands, at farmers' markets, and in food service operations (such as juice bars and restaurants).

FDA also agrees with the comment that requested that juice retailers who sell to other retailers be subject to the HACCP regulation. FDA believes that this approach will contribute to public health protection. Accordingly, under this final rule, only a retail establishment that limits its juice business to direct consumer sales would qualify for exemption from the requirements of this HACCP regulation, and would be subject to regulation by the State in which it operates. Thus, the "retail establishment" definition in this regulation is consistent with the Food Code, and also describes establishments that are included and excluded specifically for the purpose of this regulation. For example, a retail establishment, central kitchen, or processing facility that provides juice to more than one retail operation (e.g., juice production operation that provides juice to outlets of a chain supermarket) would not be considered a retail establishment that is exempt from this regulation. However, a retail establishment that produces juice for sale directly to consumers at that location and at other locations under the same ownership would be considered a retail establishment exempt from this regulation. Therefore, the agency is adding a § 120.3(l) to define a "retail establishment" as an operation that provides juice directly to consumers, and does not include an establishment that sells or distributes juice to other business entities as well as directly to consumers. "Provides" includes storing, preparing, packaging, serving, and vending. (Because the agency is establishing an additional definition in § 120.3, it is recodifying the other terms in § 120.3 so that they continue to appear in alphabetical order.)

4. Verification and Validation

(Comment 49) Several comments requested that the terms "validation" and "verification" be defined and be used consistent with NACMCF principles.

FDA agrees with the comments. The agency intends that the terms "validation" and "verification" be used consistent with NACMCF principles throughout this final rule. The NACMCF has established definitions for these terms that the agency finds useful (Ref. 17). According to the NACMCF definition, validation is a subset of verification (Ref. 17). Therefore, in this final rule the agency is amending § 120.3(p) and (q) to include the NACMCF definitions of both validation and verification as follows:

Validation means that element of verification focused on collecting and evaluating scientific and technical information to determine whether the HACCP plan, when properly implemented, will effectively control the identified hazards;

Verification means those activities, other than monitoring, that establish the validity of the HACCP plan and that the system is operating according to the plan.

C. Prerequisite Program Standard Operating Procedures

The HACCP proposal discussed two types of prerequisite program standard operating procedures (SOP's). FDA proposed to require the first type, SSOP's, in § 120.6. SSOP's cover sanitary conditions and practices before, during, and after processing. The agency requested comment (63 FR 20450 at 20466) (Ref. 2) on a second prerequisite program to provide control over materials as they enter the plant. However, the agency did not propose to require incoming material SOP's in part 120.

(Comment 50) One comment asked that if FDA requires prerequisite program SOP's, the agency should be more specific about what is to be included in the prerequisite program SOP's. It stated that some SOP's ensure wholesomeness and quality and should not be a part of HACCP.

The agency advises that it is requiring that processors implement SSOP's in part 120 at this time and not any other type of SOP. The SSOP's in § 120.6 do include specific standards that must be maintained. The SSOP's as described in § 120.6(a) address insanitary conditions and are not directed to ensure wholesomeness and quality although they may have a beneficial effect on these attributes.

1. SSOP's

(Comment 51) Several comments stated that SSOP's are covered under CGMP's and should not also be covered in HACCP and neither SSOP's nor CGMP's should be a written requirement for HACCP. One comment stated that SSOP's should not be written for the same reasons that SSOP's are not written for seafood HACCP. One comment stated that prerequisite program SSOP's should not be mandated and that CGMP's provide an adequate basis for HACCP. However, other comments maintained that SSOP's and CGMP's should be a part of written HACCP programs.

It is important to understand the difference between CGMP's, SSOP's, and HACCP. The agency has established CGMP's in part 110. These regulations provide general guidance on such matters as facility design, materials, personnel practices, and cleaning and sanitation procedures. In § 120.5, FDA requires that part 110 apply in determining whether the facilities, methods, practices, and controls used to process food are safe, and whether the food has been processed under sanitary conditions. Processors do not need to make a record of these activities for FDA review. However, the agency will continue to include in its inspections determinations of processor compliance with CGMP's. All appropriate CGMP's must be implemented, whether they are incorporated into a processor's HACCP system or not, because they reflect norms of good processing.

SSOP's are specific sanitation CGMP's that FDA has found are key to the successful implementation of a HACCP system. Not all CGMP's deal with sanitation issues (e.g., contamination with aflatoxin or other natural toxins in § 110.80(a)(3)). As required by § 120.6(a), SSOP's emphasize sanitation conditions and practices before, during, and after processing. Because of the importance of sanitation to a facility, processors must monitor SSOP conditions and practices during processing to at least ensure compliance with part 110. If sanitation conditions and practices are not met, processors must take corrective actions (§ 120.6((b)). Insanitary conditions can directly result in food hazards, especially microbiological hazards. Inadequate sanitation has a direct effect on whether the HACCP plan can adequately control food hazards. For example, insanitary conditions can cause post process contamination.

Both CGMP's and SSOP's have a broad scope. As noted in section II.A, HACCP is a system to identify specific points in a particular manufacturers process where risks exist and critical controls are needed to control the identified risks. CGMP's and SSOP's both play an important role in HACCP in that they form the foundation upon which the HACCP system is built.

FDA stated in the proposal (63 FR 20450 at 20467) (Ref. 2) that the records bearing on the monitoring of relevant sanitation conditions and practices and the agency's access to such records are essential if SSOP's are to be part of an effective regulatory strategy. Although the agency elected not to require written SSOP's under the seafood HACCP regulation, it required that seafood processors establish SSOP's and maintain records monitoring and documenting corrective actions. Juice is significantly different than seafood in that juice is generally consumed as sold whereas seafood is generally cooked, thus sanitation takes on increased importance. Because of the significance of sanitary conditions, the agency concludes that juice processors must maintain SSOP records in the same manner as that required for other HACCP records.

(Comment 52) One comment requested that FDA require that the quality and safety of water used in juice processing plants be verified.

The agency agrees that water used in juice processing plants must be safe and of an adequate sanitary quality for its intended use. This is consistent with the CGMP requirements in § 110.37(a). Section 120.6(a)(1) of this final rule requires that juice processors have SSOP's that address the safety of the water that comes into contact with food or food contact surfaces or that is used in the manufacture of ice. Processors must examine the source of the water used in their facilities and determine the necessary provisions to ensure the water's safety. The processor's particular obligations may vary, depending on the source of the water. Water from community water supplies is tested for many substances and the processor can obtain the results of that testing from the local water authority. In the case of well water, processors must know that the water they use is safe because such water could present potential hazards. Thus, processors using well water need to test the water. Moreover, if substances in the water are hazards that are reasonably likely to occur, one or more CCP's must be established and included in the HACCP plan.

(Comment 53) One comment requested that FDA require processors to monitor for water and cleaning solution contamination.

FDA believes that, given the regulation as proposed, the requested revision is unnecessary. Section 120.6(a)(1) already requires processors to have and implement SSOP's relating to water quality and § 120.6(a)(5) requires processors to have and implement SSOP's relating to the protection of food from cleaning compounds. Processors must monitor their SSOP's and take corrective actions for sanitation conditions and practices where the specified conditions are not met (§ 120.6(b)). In addition, processors must maintain records that document monitoring and any corrective actions taken (§ 120.6(c)). If either water or cleaning solution contamination is a hazard that is reasonably likely to occur, one or more control measures must be included in the HACCP plan for each hazard identified.

(Comment 54) One comment requested that FDA clarify whether § 120.6(a)(5) permits certain amounts of "no rinse" sanitizers to come into contact with product.

The agency advises that "no rinse" sanitizers used according to product directions do not present a contamination problem and, with appropriate use, their presence would not be considered a violation of § 120.6(a)(5).

(Comment 55) One comment requested that FDA set an "acceptable level of infestation" for insect control and require that processors use insect light traps as monitoring devices. Another comment requested that FDA revise § 120.6(a)(8) to read as follows: "Exclusion of pests from the food plant and prevention of contamination from pests within the plant, as well as in packaging and raw materials delivered to the plant."

FDA disagrees that it should establish an "acceptable level of infestation" for insects or that it should revise § 120.6(a)(8) as the comment requested. Exclusion of pests from the food plant is included as a necessary part of SSOP's in § 120.6(a)(8). The comment's requested modification is already implied in § 120.6(a)(8). Pests are recognized sources of microbial contamination, as well as filth, in foods. The agency believes that generally no unusual pest control requirements are necessary for juice processing operations beyond the general requirements for pest control in all food processing facilities, as laid out in part 110. However, if, during its hazard analysis, a processor identifies pests or contamination from pests as a food hazard that is reasonably likely to occur in its particular system, the processor will need to establish a control measure, critical limits, and a means of monitoring.

(Comment 56) One comment requested that FDA add the following to § 120.6(b): "The requirements under this section shall apply both to the processor's own premises and the premises of any supplier of raw materials and packaging, as far as this is relevant." The comment concluded that this is necessary because packaging and raw materials are particular sources of contamination in most food processing plants.

FDA agrees that incoming materials can be a possible source of contamination in juice processing plants but points out that the focus of this

regulation is the production of safe juice by juice processors. Nevertheless, processors are urged to take steps to control hazards before the hazards enter the processing facility. Under part 120, processors must control food hazards in the juice products they make. If a processor's hazard analysis indicates that a hazard is reasonably likely to occur in incoming materials, then an appropriate control (such as a supplier agreement concerning that hazard) must be a part of the processor's HACCP plan, and the processor must monitor the CCP and verify supplier performance. Thus, FDA concludes that raw materials and packaging are already covered adequately and is not modifying § 120.6(b) as the comment requested.

(Comment 57) One comment stated that corrective actions should not be required for CGMP's and SSOP's.

FDA advises that there are no corrective actions specifically required for CGMP's in these HACCP regulations. However, part 120 sets forth monitoring and corrective action requirements for SSOP's. Insanitary conditions create an environment in which products may become contaminated with pathogens or other substances. If a product becomes contaminated because of insanitary conditions, it is important that corrections be made as quickly as possible so as not to subject subsequently processed product to conditions that could introduce food hazards. Therefore, processors need to monitor the performance of SSOP's to ensure that the SSOP's are functioning as designed, and that any problems that arise are corrected. The comment did not provide data to persuade the agency to conclude otherwise.

(Comment 58) One comment suggested that FDA only require SSOP's in a HACCP plan if their control is essential to eliminate or control a public health risk, as determined in the hazard analysis. The comment contended that a distinction must be made between failure to meet sanitation requirements and failure to meet a food safety/HACCP requirement. The comment further stated that singling out items to be included in SSOP's implies that the other sanitation requirements in part 110 are not that important, and this is not the case. It stated that if FDA establishes SSOP's that, at the very least, no recordkeeping requirements should be associated with SSOP's.

FDA advises that processors are not required to include sanitation controls in their HACCP plans. Section 120.6(d) allows processors the option of including sanitation controls in the HACCP plan, but they are under no obligation to do so as long as the sanitation controls are being implemented through the SSOP. Insanitary facilities or equipment, poor food handling, improper personal hygiene, and similar insanitary conditions create an environment in which products may become contaminated with pathogens and other substances. A processor may determine that a task normally covered by SSOP's may be of such importance that it must be included in the HACCP plan because it controls a hazard that is reasonably likely to occur. Similarly, an SSOP task may simply be more efficiently or effectively performed under the HACCP plan rather than SSOP controls, and thus, a processor may choose to incorporate the SSOP task into the HACCP system. However, HACCP controls generally focus on discrete steps or "points" in a processing system, while sanitation and sanitation controls generally have broader, plantwide applicability. Thus, sanitation does not always lend itself well to HACCP controls. Therefore, the agency is not modifying § 120.6(d) as requested.

FDA disagrees that singling out items to be included in SSOP's implies that the other provisions of part 110 are not important. Rather, the items listed in § 120.6(a) are to assist processors in identifying and implementing key sanitation activities. Sanitation controls, such as controls preventing use of contaminated water in juice making, have a direct impact on the presence or absence of pathogens during processing, which in turn, directly affects the effectiveness of the HACCP plan. No matter how reliable the process is, insanitary conditions can cause the product to become contaminated with pathogens. It is because of the critical role that sanitation plays in the production of safe juice that FDA is requiring SSOP's, identifying specific items to be included, and requiring recordkeeping. However, processors must comply with all provisions of part 110 in addition to having SSOP's as required under § 120.5.

2. Other SOP's

(Comment 59) Several comments requested that FDA require written, monitored, and verified SOP's for incoming materials. One comment contended that reasonable procedures for these SOP's should include no use of dropped apples, no contact with water that could contain pathogens, no manure as fertilizer, steam cleaning of crates in contact with fruit between lots, and regular inspections of source farms and orchards. Another comment suggested that incoming material SOP's be required only for producers that do not pasteurize their product.

The agency is not convinced of the need for mandatory incoming material SOP's because these activities may be adequately controlled under the CGMP's in part 110. However, FDA does recognize the value of incoming material SOP's, and it encourages processors to establish and monitor incoming material conditions and practices and to take corrective actions when needed. Processors must evaluate the need for controls at all points in their process, including incoming materials. If incoming materials are reasonably likely to present a hazard, then the hazard must be controlled by one or more CCP's in the HACCP plan, even if a processor has an incoming material SOP.

Many of the controls mentioned in the comments are addressed in FDA's "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables." As noted earlier, FDA encourages farmers and processors to evaluate and modify their agricultural practices in accordance with GAP guidance. Processors may include GAP's in any SOP's for incoming materials that they may establish.

Finally, because all processors, regardless of whether or not they pasteurize, must meet the performance standard required under § 120.24, as well as the other requirements of part 120, there is no need to differentiate between processors for the purposes of requiring incoming material SOP's, and thus, to require more SSOP's from a processor that does not pasteurize.

(Comment 60) One comment requested that FDA hold a public meeting for input on incoming material SOP's.

The agency does not believe that such a public meeting is necessary. There have been many opportunities for interested parties to comment on all issues related to HACCP, including incoming material SOP's (see section I.B of this final rule). FDA requested public input in the HACCP proposed rule (63 FR 20450 at 20466) (Ref. 2) and in this final rule has considered all significant comments received. In addition, some issues surrounding incoming materials for citrus juices were discussed at the public NACMCF meeting in December, 1999 (Ref. 12). Finally, FDA intends to issue a juice HACCP hazards and controls guidance, which will provide another opportunity for public input on the incoming materials issue.

(Comment 61) One comment suggested that the GAP's for fresh produce can be used in conjunction

with SOP's to ensure the safety of incoming material.

FDA agrees that the use of GAP's in combination with SOP's may enhance the safety of incoming materials. FDA's GAP's for fresh produce provide valuable guidance for use in the production and post harvest handling of raw agricultural commodities. As noted, the agency also intends to publish a juice HACCP hazards and controls guidance that will provide additional guidance on ensuring the safety of incoming materials.

(*Comment 62*) One comment stated that HACCP should include a requirement for incoming materials testing to prevent another outbreak like the one in 1996.

The agency disagrees that it should require incoming materials testing in part 120, although it encourages processors to test incoming materials as appropriate. Testing may be used as a control measure for a hazard that is reasonably likely to occur and it may also be used to gather information on a product or supplier for use in the hazard analysis. However, testing may not be useful in all cases. Microbial contamination of fresh produce is usually at low levels and is not uniformly distributed throughout a lot. Thus, while detecting a pathogen, such as *E. coli* O157:H7, would allow a processor to avoid using contaminated produce, failure to detect pathogens by testing does not provide assurance that the hazard is not present in incoming materials. The 5-log reduction in the pertinent pathogen as implemented in a HACCP system provides the assurance that microbial hazards are under control throughout the process. Therefore, the agency is not requiring the testing of incoming materials.

D. Hazard Analysis

The agency proposed in § 120.7 that processors develop a written hazard analysis to determine whether there are hazards that are reasonably likely to occur for each type of juice produced by a processor and to identify the control measures that the processor can apply to control those hazards.

(*Comment 63*) One comment requested that FDA clarify how a hazard analysis is conducted. The comment suggested that FDA emphasize the NACMCF recommendations, including consideration of both likelihood of occurrence and severity of hazards. The comment expressed concern that without considering both the likelihood of occurrence and severity of hazards, HACCP plans would not be consistent with international practice and World Trade Organization (WTO) obligations, which state that scientific determinations of risk are needed to form a sound basis for food safety standards.

The agency agrees that the approach outlined by the NACMCF will best assist processors in conducting a hazard analysis. First, processors will benefit from using the five preliminary steps set forth by the NACMCF, which are to assemble a HACCP team, describe the food and its distribution, identify the intended use and consumers of the food, develop a flow diagram that describes the process, and verify the flow diagram (Ref. 17). Although the agency is not specifically requiring that processors use these preliminary steps, these steps will aid processors in focusing on their specific product and process.

According to the NACMCF, processors must accomplish three objectives in the hazard analysis: (1) Identify hazards that are reasonably likely to occur and their associated control measures; (2) identify needed modifications to a process or product so that product safety is further assured or improved; and (3) provide a basis for determining CCP's in the HACCP plan (Ref. 17). FDA agrees with these objectives.

The first NACMCF objective is accomplished in three steps. First, processors must list all the potential hazards that could be present in the juice. During this step, the processor's HACCP expert or team reviews the ingredients used in the product, the activities conducted at each step in the process and the equipment used, the final product and its method of storage and distribution, and the intended use and consumers of the product. A list of categories of potential food hazards is found in § 120.7(c). Based on this review, the processor's HACCP team develops a list of potential biological, chemical, or physical food hazards that may be introduced, increased, or controlled at each step in the production process. A hazard analysis must be conducted for each type of juice product manufactured by the processor because different hazards may be associated with different juice products. (For example, patulin need only be considered in apple juice products.)

The processor must then identify those food hazards that are reasonably likely to occur. According to NACMCF, this step takes into account both the consequences of exposure (i.e., severity) and the probability of occurrence (i.e., frequency) of the health impact of the potential hazards in question (Ref. 17). FDA agrees with the NACMCF approach. Accordingly, when applying the phrase "reasonably likely to occur," a processor must consider both severity and frequency of potential hazards. The NACMCF stated that consideration of the likelihood of the hazard's occurrence is usually based upon a combination of experience, epidemiological data, and information in the technical literature (Ref. 17). The NACMCF also stated that consideration should be given to the effects of short term, as well as long-term, exposure to the potential hazards. Because this process takes into consideration both frequency and severity, a potential hazard may be identified as reasonably likely to occur even though it occurs infrequently because the public health consequences when it does occur are so severe, *e.g.*, HUS in small children from *E. coli* O157:H7 in juice. This approach also provides greater harmony for international trade because it is the same approach recommended by the Codex Alimentarius Commission, which is a recognized standard setting body by the WTO. Hazards that are not reasonably likely to occur do not require further consideration within a HACCP plan but are controlled under CGMP's.

Identification of control measures is a third step in the first NACMCF objective in developing a hazard analysis. For example, juice processors must identify the process they will use to achieve the 5-log reduction in the pertinent pathogen. This may be pasteurization, surface treatments for citrus, or other effective methods. Therefore, § 120.7 requires that processors identify the measures that they will apply to control the hazards that have been identified as reasonably likely to occur. These control measures must be included in the HACCP plan as well as the hazard analysis.

Under the second NACMCF objective, processors must review their current process to determine deficiencies in controlling food hazards and then identify the changes that must be made to ensure that food hazards are controlled. For example, some juice beverages may be thinner or thicker than others, a characteristic that may affect how fast the product flows through the pasteurizer; in this stage of the hazard analysis, the processor must review its process to determine whether the product is flowing through the pasteurizer at a rate sufficient to ensure that all particles of the juice receive the appropriate treatment in terms of both time and temperature to achieve, at a minimum, the 5-log reduction in the pertinent pathogen.

The third NACMCF objective requires that processors use the hazard analysis to provide a basis for determining CCP's in the HACCP plan. For example, some

processors may run different juice beverages on the same line during the same day with only a water flush between products. If one juice product contains a potential allergen, such as a soy ingredient, then a possible control measure is that this product be run last in the day with a thorough cleaning of the system before the next day's startup.

To clarify the necessary steps in developing a hazard analysis, as the comment requested, the agency is codifying them in § 120.7(a). (Because the agency is adding these steps to § 120.7, it is recodifying the other paragraphs in § 120.7 for clarity.)

(Comment 64) A few comments objected to the requirement of a written hazard analysis because the seafood HACCP regulation does not require a written hazard analysis. However, some comments supported such a requirement.

FDA acknowledges that a written hazard analysis is not required by the seafood HACCP regulation and believes that, at the time that the regulation was established, this was appropriate. Although the seafood HACCP regulation does not require a written hazard analysis for agency record review, seafood processors are strongly urged to have a written hazard analysis to resolve differences between the processor and the agency about whether a HACCP plan is needed and about the selection of hazards, CCP's, and CL's.

Since the issuance of the seafood HACCP regulation, the HACCP concept and how best to implement HACCP has evolved in step with industry's increasing experience with HACCP; part of that evolution is the idea that the hazard analysis should be written. Processors will have a better HACCP system if they document the hazard analysis process. A thorough hazard analysis is the key to preparing an effective HACCP plan. According to the NACMCF, if the hazard analysis is not done correctly and the hazards warranting control are not properly identified, the plan will not be effective regardless of how well it is followed (Ref. 17).

Another aspect of HACCP implementation that affects the need for a written hazard analysis is the availability of specially trained investigators. At the time the seafood HACCP program was established, FDA had sufficient resources to hire and specifically train investigators in seafood HACCP, as well as to provide assistance to the industry in implementing HACCP. With expansion of HACCP into other commodity areas, the agency does not have the resources to develop cadres of investigators with expertise in a single commodity, such as juice. With a written hazard analysis, investigators can more easily determine whether processors have adequately considered all juice hazards and have adequately identified those hazards that are reasonably likely to occur.

Even though a written hazard analysis is not required by the seafood HACCP regulation, that regulation, as well as USDA's meat and poultry HACCP regulations, require a systematic and comprehensive hazard analysis. In addition, USDA's meat and poultry HACCP regulations require a written hazard analysis. Thus, the only difference in the juice final rule and the seafood HACCP regulation is that the analysis is written, not that it is or is not required. FDA believes that the additional step of recording the hazard analysis poses no significant burden, economic or otherwise, to juice processors and, on the contrary, has advantages for the processor. A written hazard analysis provides processors with a ready record of the decisions made in conducting a safety analysis of their process, which they may use in evaluating potential changes to the system and for discussions with regulatory officials. Further, written hazard analyses are useful to processors in that they help provide the rationale for the establishment of critical limits and other plan components. Having the basis for these decisions available will be helpful when processors experience changes in personnel, especially those associated with the HACCP process, and in responding to unanticipated CL deviations.

A written hazard analysis need not be a highly detailed document, but it must reflect consideration of all the potential hazards that could occur in a processor's system for a product and the processor's decisions about whether these hazards are reasonably likely to occur. The hazard analysis may be as simple as a checklist of potential hazards and the reason why certain decisions were made. A written hazard analysis clearly and rationally demonstrates that processors have considered all potential hazards, identified those hazards that are reasonably likely to occur and are associated with their product and process, and identified CCP's and CL's in their HACCP plan.

(Comment 65) Several comments stated that HACCP should only cover hazards that are reasonably likely to occur and that have been documented.

FDA agrees that processors need only control in their HACCP plan those hazards that are reasonably likely to occur and that have been documented. The hazard analysis is where processors differentiate between unlikely hazards and hazards that are reasonably likely to occur in the absence of controls. This determination is made for each type of juice processed in a particular facility. Data such as experience, illness data, scientific reports, or other information may be used as documentation as to whether the hazard is reasonably likely to occur in juice and, if so, how the hazard is best controlled.

(Comment 66) One comment requested that the agency revise proposed § 120.7(a) to state generally that all physical, chemical, and microbiological hazards be considered, instead of providing a numbered list of potential hazards to be considered in the hazard analysis.

FDA disagrees that all physical, chemical, and microbiological hazards must be considered, but only those that can be introduced both within and outside the particular processing environment, including hazards that can occur before, during, and after harvest. The agency points out that the provision now codified as § 120.7(c), simply provides guidance in the form of a minimum list of potential physical, chemical, and microbiological hazards that processors should consider. The list is not intended to be all-encompassing, and is not so constructed. FDA believes that this guidance is useful because it provides detail about the types of potential hazards that fall into the more general categories of physical, chemical, and microbiological hazards. For these reasons, FDA declines to revise § 120.7(c) as requested.

(Comment 67) Several comments argued that unapproved pesticide residues, unapproved food and color additives, and food allergens are not appropriate for inclusion in HACCP because, categorically, they are not a significant threat to public health and are already covered by other regulations. One of the comments supported its claim of inappropriateness by pointing out that FDA failed to give any examples of problems caused by unlawful pesticide residues or unapproved food and color additives. Therefore, it stated, these are not problems that should be covered by HACCP, but addressed under CGMP's.

FDA disagrees that certain types of potential hazards, such as those mentioned in § 120.7(c), need not be considered in a hazard analysis. For example, pesticide residues above tolerance may be potential hazards. However, it is unlikely that pesticide residues above tolerance will need to be identified during a hazard analysis as hazards that must be included in the

HACCP plan because they occur infrequently and the public health impact of infrequent exposure is not severe.

The agency recognizes that there are effective governmental control programs in place in the United States to assure generally that unlawful pesticide residues are unlikely to occur. For pesticides, these controls include pesticide registration, applicator licensure, and government sampling and enforcement programs. Likewise, unapproved food and color additives are generally unlikely to occur in juice products because prudent processors would not intentionally add them to their products. Thus, for crops grown in the United States, a processor may ordinarily conclude that the controls for pesticide use are such that it is not reasonably likely that unlawful pesticide residues will be present in crops (including residues at levels above tolerance). A processor is responsible for assessing the adequacy of control for pesticide use for crops grown outside the United States and determining whether such controls are sufficient to make it unlikely that unlawful pesticide residues will be present. If foreign governmental controls are sufficient, HACCP controls would not likely be necessary in the processor's HACCP plan. If foreign governmental controls are not sufficient, the processor may need to include appropriate controls in its HACCP plan.

Similarly, unapproved food and color additives would be reasonably likely to occur only if, because of their presence in the production plant and the potential for formulation errors, there was a real likelihood that they may be inadvertently added to the product or added at higher than the allowable rate. A food or color additive may also be used on the product by a processor's supplier. This may pose a hazard where the food or color additive is a potential allergen or causes sensitivity reactions in susceptible individuals. For example, a processor may make several types of juice drinks, some containing FD&C Yellow No. 5. The likelihood and severity of a reaction to Yellow No. 5 is a factor that must be considered in determining whether the unintended presence, whether by misformulation or cross contamination, of the ingredient or additive in a food is reasonably likely to occur and, therefore, constitutes a potential hazard.

Therefore, the agency concludes that if unlawful pesticide residues and unapproved food and color additives are hazards that are reasonably likely to occur, it is appropriate that a processor identify them in its hazard analysis and include them in its HACCP plan.

(Comment 68) Several comments suggested that pesticide control should be handled as an agreement between processor and grower, not as a CCP.

The agency advises that if an agreement between a processor and a grower adequately assures that unlawful pesticide residues will not be a hazard that is reasonably likely to occur, then controls for that particular hazard need not be included in the HACCP plan. Agreements between processors and growers on pesticide issues may be particularly useful for produce grown in areas where government controls may not be sufficient to ensure that unlawful pesticide residues are not a hazard that is reasonably likely to occur.

(Comment 69) One comment noted that unapproved food and color additives are not an issue for orange juice because it has a standard of identity.

The existence of a standard of identity, such as for orange juice or tomato juice, is no guarantee that an unapproved food or color additive has not been intentionally or inadvertently added to the juice product. However, as noted previously, if a processor's hazard analysis establishes that unapproved food and color additives are not a hazard that is reasonably likely to occur, such additives do not need to be controlled as part of a HACCP plan.

(Comment 70) One comment requested that proposed § 120.7(b) be withdrawn as the list of what a processor should evaluate because it is already covered under part 110 and can be addressed by prerequisite programs.

The agency stated in the proposal that it was including in proposed § 120.7(b) (now codified as § 120.7(d)) some elements that would be useful for juice processors to consider in a hazard analysis (63 FR 20450 at 20468) (Ref. 2). Although CGMP's and SSOP's address a wide variety of situations and hazards, a particular food hazard may be reasonably likely to occur in the absence of its control and, therefore, necessitate HACCP controls. To assist processors in identifying all hazards that are reasonably likely to occur in their products, and their public health impact, FDA is, therefore, retaining the list in § 120.7(d) to guide processors in their hazard analyses.

(Comment 71) One comment requested that FDA revise the list of what processors should consider in evaluating the safety of their products to include cooling, ice, and water quality specifically.

The list in § 120.7(c) simply provides examples to guide processors and is not intended to be all inclusive. Ice and water quality are issues that generally will be addressed in the SSOP requirement in § 120.6(a)(1). Therefore, the agency is not modifying § 120.7(c) as requested. However, because the list in § 120.7(c) is guidance for processors, it does not preclude a processor from considering ice and water quality in its hazard analysis. If ice or water quality poses a hazard that is reasonably likely to occur, then the hazard must be addressed in the HACCP plan.

E. HACCP Plan

The agency proposed that processors have and implement a written HACCP plan for a given process whenever a hazard analysis of that process establishes that there are one or more food hazards that are reasonably likely to occur during such processing. The written HACCP plan is to include the following seven principles: (1) Conduct a hazard analysis, (2) determine the critical control points, (3) establish critical limits, (4) establish monitoring procedures, (5) establish corrective actions, (6) establish verification procedures, and (7) establish recordkeeping and documentation procedures. These seven elements are derived from the NACMCF principles of HACCP.

(Comment 72) One comment requested that FDA delete the term "during processing" in § 120.8(a) because some of the problems in the past have come from fruit contaminated on receipt and the term could be read to mean that only hazards that could occur during processing should be considered in the hazard analysis.

The agency does not agree with the comment. Section 120.7 requires that processors conduct a hazard analysis to determine the hazards that are reasonably likely to occur in their juice. If a hazard is reasonably likely to occur in the juice, the source of the hazard is immaterial. Therefore, FDA is not revising § 120.8(a) to delete the term "during processing."

(Comment 73) One comment requested that FDA delete proposed § 120.8(b)(2)(ii) because it appears to contradict the definition for processing in proposed § 120.3(h)(1) (finalized as § 120.3(j)(1)). The comment asserted that § 120.8(b)(2)(ii) states that CCP's should include food hazards that occur before, during, and after harvesting, yet processing is defined as excluding harvesting, picking, or transporting raw materials, which places it beyond the control of a processor.

The agency is not making the requested change because the language in question, along with the definition of

processor in § 120.3(k), serves to identify those who are required to comply with part 120 and is not a basis for excluding potential food hazards from consideration. Specifically, the definition of processing in § 120.3(j)(1) excludes the activities of harvesting, picking, or transporting raw materials even if these materials may be intended for use in juice processing under § 120.3(k). Only those engaged in "processing" juice are "processors" and are subject to the requirements in part 120. However, juice processors are responsible for addressing the hazards that may be present in/on the foods produced during their process, including hazards that result from characteristics of the incoming produce. One way to address potential hazards presented by incoming materials is by examining those materials when received and rejecting those that may contain hazards. Another way is to process juice in a manner to control pathogens or other hazards that may have been present on incoming materials. Therefore, FDA believes that the definition of "processing" does not conflict with § 120.8(b)(2)(ii) and is not making the requested change.

F. Legal Basis

The agency proposed in § 120.9 that failure of a processor to have and to implement a HACCP system that complies with §§ 120.6, 120.7, and 120.8, or otherwise to operate in accordance with the requirements of this part, renders the juice products of that processor adulterated under section 402(a)(4) of the act (21 U.S.C. 342(a)(4)).

(Comment 74) A number of comments asserted that FDA lacks the statutory authority to require juice processors to establish HACCP programs. Several comments claimed that section 402(a)(4) of the act cannot be read to authorize a broad range of HACCP controls and to provide that the failure to observe any of those controls would render food prepared under such conditions adulterated within the meaning of section 402(a)(4) of the act.

FDA disagrees with these comments. As shown below, the agency has ample authority to require juice processors to establish HACCP systems.[4]

FDA is issuing these regulations under the authority of the act and the Public Health Service Act (PHS Act). Specifically, FDA is relying on sections 402(a)(4) of the act and 701(a) of the act (21 U.S.C. 371(a)) and section 361 of the PHS Act (42 U.S.C. 264).

Under section 402(a)(4) of the act, a food is adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health. It is important to recognize that section 402(a)(4) of the act addresses conditions that may render a food injurious to health, rather than conditions that have actually caused the food to be injurious. See *United States* v. *1,200 Cans, Pasteurized Whole Eggs, Etc.*, 339 F. Supp. 131, 141 (N.D. Ga. 1972). *See also United States* v. *H.B. Gregory, Co.*, 502 F.2d 700, 705 (7th Cir. 1974), *cert. den.* 422 U.S. 1007 (1975). As noted in the notice of proposed rulemaking, 63 FR 20450 and 20457 (Ref. 2), the question is whether the conditions of a juice processing operation are such that it is reasonably possible that the juice produced by that operation may be rendered injurious to health. Based upon the information available to the agency and filed in the record of this proceeding, FDA has concluded that, if a juice processor does not incorporate certain basic controls into its procedures for preparing, packing, and holding juice, it is reasonably possible that the juice may be rendered injurious to health and, therefore, adulterated under the act. FDA is authorized by 21 U.S.C. 371 to adopt regulations for the efficient enforcement of the act.

FDA believes that the comments disputing the agency's authority to issue these regulations advocate an unduly narrow interpretation of the act generally and of section 342(a)(4) specifically. It is well-settled that the act is to be interpreted broadly so as to achieve its goal of public health protection. *United States* v. *Bacto-Unidisk*, 393 U.S. 784, 798 (1969). Section 402(a)(4) of the act deems adulterated food that is prepared, packed, or held under "insanitary" *conditions*. The term "insanitary" is not defined in the act. "Sanitary" describes that which "pertains to health, with especial [sic] reference to cleanliness and freedom from infective and deleterious influences," Black's Law Dictionary, 6th Ed.(1990); use of the prefix "in" denotes the absence or opposite of sanitary. Thus, "unsanitary conditions" are those that contribute to unhealthiness generally, including unclean conditions or those that promote infection or disease.

The case law interpreting section 402(a)(4) of the act is consistent with this broad reading of "insanitary conditions." In particular, in *United States* v. *Nova Scotia Food Products Corp.*, 568 F.2d 240 (2d Cir. 1977), the Second Circuit rejected a restrictive reading of 402(a)(4) of the act, concluding that this section provided the FDA with authority to establish by regulation processing parameters to control or eliminate harmful substances present in food intended for further processing. *See United States* v. *Nova Scotia Foods*, 417 F.S. 1364, 1368–1369 (E.D.N.Y. 1976), *aff'd supra*, 568 F.2d 240. At issue in *Nova Scotia* were FDA's regulations governing the time, temperature, and salinity for processing smoked fish, 568 F.2d at 243, 247 to 248, and provisions designed to minimize the outgrowth and toxin formation of *Clostridium botulinum Type E*, 568 F.2d at 243. The regulations in question defined sanitary conditions for processing such fish; fish processed under conditions not complying with the regulation were deemed adulterated within the meaning of section 402(a)(4) of the act, 21 CFR 128a.2 (1971); 35 FR 17401 (November 13, 1970) (Ref. 60). Although the Court posited that "insanitary conditions" could be narrowly interpreted to refer to insanitary conditions in the plant, such as the presence of insects and rodents, the Court rejected this narrow interpretation, 568 F.2d at 245 to 246, and held that under section 402(a)(4) of the act, "insanitary conditions" may include "inadequate sanitary conditions of prevention" (568 F.2d at 247). In rejecting the narrower reading of 402(a)(4) of the act, the Court recognized a "larger general purpose on the part of Congress in protecting the public health" (568 F.2d at 248).

This final rule requires that juice processors implement and maintain HACCP systems. As discussed in detail above, HACCP systems are designed to prevent, control, or eliminate hazards that are reasonably likely to occur during food production, including hazards that are present in in-coming materials, such as pathogens and other contaminants. Under the final rule, § 120.9, the failure of a juice processor to establish and maintain an adequate HACCP system renders juice produced under that system adulterated within the meaning of section 402(a)(4) of the act. Thus, the provisions of this final rule are essentially comparable to those addressed in *Nova Scotia*.

In addition, FDA relies on its authority under the Public Health

[4] Comments on the seafood HACCP final rule raised similar questions as to FDA 's authority to require seafood processors to establish HACCP systems and to require recordkeeping and record access. In response to the proposed juice HACCP rule, one trade associations filed a copy of its comments on the seafood HACCP proposal. The agency 's detailed response to the comments on the seafood proposal, set out at 60 FR 65098 –65012, is incorporated by reference into the preamble of this final rule

Service Act in issuing this regulation to the extent that the regulation seeks to control illnesses caused by pathogenic microorganisms. Under section 361 of the PHS Act (42 U.S.C. 264), the Surgeon General is authorized to issue and enforce regulations to prevent the introduction, transmission, or spread of communicable diseases from one State to another State; this authority has been delegated to the Commissioner of Food and Drugs, 5 CFR 5.10(a)(4). See *State of Louisiana* v. *Mathews*, 427 *F. Supp. 174, 176 (E.D. La. 1977)*. The record in this rulemaking amply demonstrates that juice can function as a vehicle for transmitting food-borne illness caused by pathogens such as *Salmonella* and *E. coli* O157:H7. Juice produced in one State and shipped and sold in another State may be contaminated with pathogens and thus may result in the transmission of food-borne illness from State to State. The record similarly establishes that juice may be produced and sold to a visiting consumer in one State, with the consumer subsequently taking the juice to a second State. Given that juice can function as a vehicle for transmitting human pathogens, this situation creates the possibility that food-borne illness will be transmitted from one State to another. In light of the record of this proceeding, FDA has concluded that a system of HACCP controls is necessary to prevent the spread of communicable disease via consumption of contaminated juice, and that the PHS Act provides the agency with the authority to establish such HACCP requirements for juice.

(Comment 75) Several comments challenged the agency's authority to require that certain records be maintained and that FDA be granted access to those records The thrust of these comments is that the act does not explicitly authorize the agency to require food processors to maintain records or to require access to records maintained by food processors. The comments observed that section 704 of the act (21 U.S.C. 374), the act's general records access provision, contains specific authorization for agency access to records relating to drugs and restricted medical devices but that, by its terms, the authority of section 704 does not extend to records relating to foods. Thus, the comments conclude that the records access provisions of the juice HACCP proposal are unlawful.

FDA disagrees with this comment because the agency has adequate authority under the act and the PHS Act both to require the maintenance of records and to compel official access to such records for the efficient enforcement of the act. Importantly, FDA is not relying on its authority in section 704 of the act to require the keeping of HACCP records and to require official access to such records. As discussed in the response to the previous comment, in terms of the act, this final rule implements section 402(a)(4) and utilizes FDA's authority in section 701(a) of the act to issue regulations for the efficient enforcement of the act. FDA is similarly relying on sections 402(a)(4) and 701 to establish the recordkeeping and access to records requirements of this rule. That this is sufficient authority is established in the caselaw.

In particular, in *National Confectioners Assoc.* v. *Califano*, 569 F.2d 690 (D.C. Cir. 1978), the D.C. Circuit held that FDA had authority to establish recordkeeping requirements for food processors. In *Confectioners*, the recordkeeping provisions of the regulations were challenged on the grounds that they would permit prosecution where processing conditions were completely sanitary, but required records were deficient. Such an outcome, it was argued, would be beyond the scope of section 402(a)(4) of the act, one of the particular sections relied upon as authority for the regulation as a whole. The court rejected this argument, holding that the principal consideration was whether the statutory scheme as a whole justified the regulations. Although the records in question in Confectioners were coding and distribution records that FDA desired in order to facilitate recalls, the court's ruling as to the validity of the regulations was not limited to recalls or shipping records. Indeed, *Confectioners* is appropriately read to authorize FDA to establish regulations that have a limited scope, are not unreasonably onerous, and clearly assist in the efficient enforcement of the act (569 F.2d 693 n. 9). In addition, the *Confectioners* court recognized that FDA has a role both in preventing and in remedying commerce in adulterated foods, and that the act imposes on the FDA an equal duty to perform each role (569 F.2d at 694).

It is widely accepted that recordkeeping and inspectional access to records are essential components of a HACCP-type system. Through records maintenance and review, a processor can, over time, develop a comprehensive picture of its process and identify shortcomings or potential shortcomings. Similarly, records maintenance and access provide the appropriate regulatory authorities with the opportunity to oversee, in a comprehensive way, the operation of the processor's HACCP plan, thereby ensuring that contaminated juice products will not enter the marketplace.

Like the records at issue in *Confectioners*, the records at issue with respect to this final rule are designed to prevent the introduction into commerce of adulterated foods (569 F.2d at 694). In this case, the recordkeeping and access required under this final rule meet the *Confectioners* test. First, the requirements are limited. The HACCP recordkeeping and record access requirements in the final rule are tied specifically to the CCP's, i.e., those points in the process at which control is essential if there is to be assurance that the resultant product will not be injurious to health is to be achieved. Second, this limited amount of recordkeeping assists FDA in the efficient enforcement of the act. By focusing on the CCP's, the requirements ensure that the processor and the agency focus on those aspects of processing that present the greatest threat to food safety; by documenting whether the HACCP plan and its preventive controls are being followed, these records enable regulators to verify proper operation of the HACCP system or identify malfunctioning of the system, again ensuring that adulterated foods are not produced and distributed to consumers. As such, the record-keeping requirements assist in the effective and efficient enforcement of the act. Finally, the HACCP recordkeeping burden is not unduly onerous because the required records are limited to the development of appropriate controls and documenting those aspects of processing that are critical to food safety. The documentation required in the final rule is narrowly tailored to ensure that only essential information needs to be recorded and maintained. Because the preventive controls required by HACCP are essential to the production of safe food as a matter of design, the statutory scheme is benefited by agency access to records that demonstrate that these controls are being systematically applied.

Similarly, FDA's authority under the PHS Act (42 U.S.C. 264), provides a separate and sufficient basis for the recordkeeping and records access provisions of this rule, at least to the extent that these requirements relate to the transmission of communicable disease. The record of this proceeding clearly shows that juice can function as a transmitter of human disease caused by foodborne pathogens, such as *Salmonella* and *E. coli* O157:H7. Likewise, the record demonstrates that a system of preventative controls, such as those based upon HACCP, will control or eliminate this risk from juice

consumption. As discussed in more detail below, records for the HACCP operation, and official access to these records, are central to the effectiveness of HACCP. Thus, the PHS Act clearly authorizes the records maintenance and access requirements of this final rule.

(Comment 76) A few comments stated that the factual and legal justifications for mandatory HACCP relate to the presence of pathogens in the final product, which is not true of the pasteurized juice industry. Comments maintained that section 402(a)(4) of the act does not authorize a broad range of controls and that seafood HACCP was predicated on the conclusion that there were sufficient hazards in all fishery products. One comment stated that the factual predicate relied upon in the seafood rule does not exist for juice. The comment maintained that a review of the data in the proposed rule indicates that microbiological hazards gave rise to the entire HACCP proceeding and these hazards do not exist in pasteurized and shelf stable juices.

The agency addressed the legal authority for this rule in the response to comment 74. FDA disagrees that the factual predicate for juice HACCP is not adequate. The record demonstrates that there are significant potential hazards in the production of juice, including pasteurized and shelf stable juices. These potential hazards in juice can be divided along the lines of the NACMCF food hazard definition: Microbiological, chemical, and physical. Microbiological hazards can be controlled with some type of heat treatment or other process that prevents, reduces, or eliminates the pathogens. Chemical hazards are not normally affected by heat and other treatments that are used to reduce the microbial contamination of foods and thus, must be controlled by other means (*e.g.*, rejection of incoming materials with high lead levels). Likewise, physical hazards must be controlled in some manner other than by thermal or equivalent treatments. All three types of hazards require that the specific hazard be identified (*e.g.*, bacterial species; mycotoxin identity; foreign matter present, such as glass), a means for preventing or controlling the hazard identified, and the means of control consistently and effectively used. The public health effects of microbial hazards are most often acute, although long-term, chronic effects have been identified (*e.g.*, arthritis). Chemical hazards are most often associated with chronic adverse health affects, although they may also have immediate, acute affects (*e.g.*, excess tin leaching from container lining can cause vomiting). Physical hazards cause acute health affects, such as cuts in the mouth from glass or metal fragments in the food. These hazards are discussed in more detail below.

Microbial hazards—There is a long history of foodborne illness outbreaks associated with microbial contamination of a variety of juices. The public health consequences may be minimal (some gastrointestinal distress), severe (hospitalization, HUS), or fatal. Among the pathogens that have been associated with juices are *E. coli* O157:H7, *Salmonella, Cryptosporidium*, and certain viruses. Identified sources of pathogens include water, fruit, processing under insanitary conditions, and infected workers and food handlers.

Juices, particularly fruit juices, have traditionally not been considered vehicles for human pathogens. Fruit juices, in particular, are acidic, and such acidity generally would inhibit the growth of most pathogens. Over the past few decades, however, it has become well documented that some pathogens have adapted to this acidic environment, making juices susceptible to microbial contamination and subsequent survival of the pathogens in the juice products.

Regarding the comment that pasteurized juices should not be subject to HACCP, is without foundation because "pasteurized" products may potentially contain chemical or physical hazards. HACCP systems control all types of food hazards, not just the microbial hazards that adequate heat treatments will control. In recognition of the lethality of the heat treatment that shelf stable and concentrated juice products receive, FDA has modified the pathogen control requirements in § 120.24 for these product groups. This modification to the proposed rule is discussed in detail in the response to comment 140.

Chemical hazards—There is also a history of foodborne illness outbreaks caused by a variety of chemical hazards in foods. These hazards include the presence of tin, lead, and poisonous plant materials. FDA recall data show that additional types of chemical substances with the potential to cause illness or injury have triggered recalls of products from the market (*e.g.*, food ingredients that cause allergic-type reactions such as FD&C Yellow No. 5), cleaning solutions, copper from copper pipe fittings on processing equipment. Symptoms of reported juice outbreaks usually are limited to acute gastrointestinal effects. Chronic effects of chemical contaminants are difficult to assess because long-term monitoring of the health of individuals that experience illness or injury caused by chemical hazards is required and there are no data indicating that this type of monitoring occurs. Some chemical hazards, such as patulin, have known chronic effects of sufficient public health concern that FDA is in the process of issuing guidance documents concerning maximum levels that should be present in foods (Refs. 19 and 24).

Sources of chemical contaminants in juices include packaging materials, plant (botanical) material, processing and cleaning equipment, formulation errors, contaminated ingredients, and contaminated fruit (*e.g.*, patulin in apples). Unlike microbial contaminants, chemical contaminants cannot be destroyed or easily removed from contaminated foods, and thus, appropriate controls must be established to prevent the contamination in the first instance.

Physical hazards—FDA recall data indicate that glass and fragments of other packaging materials frequently cause companies to recall juice products. However, the agency has no data on illnesses or injuries caused by those packaging materials.

(Comment 77) One comment stated that *United States* vs. *Nova Scotia Foods Products Corporation* cannot be read to authorize HACCP controls. The comment maintained that this case cannot be said to support FDA's proposal to impose a complex and detailed regulatory scheme on pasteurized products. Additionally, the comment stated that since FDA cannot demonstrate a need or legal justification for HACCP for pasteurized products, its authority to require recordkeeping and record inspection under such a HACCP program has no statutory basis.

In the response to comment 74, the agency has explained at some length the basis for its reliance on *United States* v. *Nova Scotia Foods*, 417 F.S. 1364, 1368–69 (E.D.N.Y. 1976), *aff'd supra, 568 F.2d 240*. Similarly, in the response to comment 75, FDA has explained at length the legal basis for the recordkeeping and records access provisions of this final rule. In sum, both the rule itself and the recordkeeping provisions are clearly authorized by the act and the PHS Act.

G. Corrective Actions

FDA proposed to require in § 120.10 that processors take appropriate corrective actions whenever a deviation from a critical limit occurs. All corrective actions must be fully documented in records and are subject to verification under § 120.11(a)(iv)(B).

(Comment 78) One comment requested that FDA revise § 120.10(a)(1)

and (b)(3) to remove the wording "otherwise adulterated" because it broadens the scope of the rule beyond food safety and the focus of HACCP should be on food safety. The comment further stated that adulteration is covered in part 110 and should not also be covered in part 120.

The agency disagrees that the requested revisions are necessary. HACCP plans only address food hazards that are reasonably likely to occur. Under § 120.3(g) a "food hazard" is defined as "any biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control." Thus, a HACCP plan is already focused on food safety. FDA also disagrees that adulteration is addressed exclusively by part 110. In fact, the legal basis for this final rule is, in part an adulteration provision, 402(a)(4) of the act and juice not processed under conditions not complying with this final rule is adulterated (see § 120.9).

(Comment 79) A few comments suggested that in § 120.10(b)(5) the words "timely validation" probably should be "timely verification" or "timely review" and that in § 120.13(a)(3) the term "verifying" should be used in place of "validating" to be consistent with NACMCF's HACCP guidelines.

The agency agrees with the comments. When there is a process deviation, processors must undertake a review to see if there have been sufficient changes such that a revalidation of the HACCP plan is warranted. The fact that processors have discovered a deviation indicates that the HACCP plan is working. Therefore, FDA is modifying § 120.10(b)(5) to use the term "timely verification" and § 120.13(a)(3) to use the term "verifying." As noted previously, the agency is defining the terms "validation" and "verification," in § 120.3(p) and (q), respectively.

H. Verification and Validation

(Comment 80) One comment requested that FDA not require a review of consumer complaints in the HACCP program. The comment maintained that review of consumer complaints is untimely because the product has already been processed and reached the consumer. Additionally, the comment stated that consumer complaints, or lack thereof, cannot attest to the effectiveness of a process. Another comment suggested that it should be up to the management to determine which consumer complaints need followup in relation to HACCP compliance. One comment stated that only consumer complaints that indicate a deviation should be held for HACCP review.

The agency disagrees that processors should not review consumer complaints as part of their HACCP programs. The agency recognizes that review of consumer complaints is of limited use as a preventive tool because the consumer making the complaint already has the product. However, such review may alert the processor to a problem that, if resolved, would prevent recurrence of the problem with other consumers. The agency also recognizes that the receipt or absence of complaints does not alone attest to the adequacy of a HACCP system. However, it is FDA's experience that consumer injury or illness complaints can identify problems traceable to inadequate controls at the food processing facility (Ref. 61). Where information that has potential relevance to food safety is available to a processor as a result of its own consumer complaint system, it is entirely appropriate for the processor to consider that information in assessing the adequacy of its HACCP program. FDA concludes, therefore, that processors should evaluate, as part of their HACCP verification procedures, the consumer complaints that they receive to determine whether the complaints relate to the adequate performance of control measures or reveal unidentified hazards.

FDA agrees that it is up to management to determine which consumer complaints need followup in relation to HACCP compliance as part of its verification procedures. This final rule does not require that processors hold consumer complaints for HACCP record review, except as the processor deems necessary as documentation of verification procedures.

(Comment 81) One comment requested that FDA revise § 120.11(a)(1)(iii) by adding at the end of the sentence "where these are other than standard operating procedures or CCP's" to clarify that testing required under standard operating procedures or CCP's is not optional.

The agency disagrees that the requested revision of § 120.11(a)(1)(iii) is appropriate. The requested revision would make the testing mandatory as part of verification activities for SOP's and CCP's. This was not the intent of the provision. In the preamble to the proposal, the agency acknowledged the shortcomings of end-product testing as a process control, especially microbiological testing, but encouraged inclusion of testing in HACCP systems where it is appropriate. SOP's and CCP monitoring requirements do not necessarily need to be end-product or in-process tested, except where FDA is requiring end-product testing. Monitoring could consist of ensuring that the product was processed within time/temperature parameters or time/sanitizer concentration parameters. Therefore, FDA is not making the requested modification.

(Comment 82) One comment suggested that verification should include actual times and temperatures taken and recorded and that there should be penalties for noncompliance.

The agency agrees with the comment. Verification activities include timely review of monitoring records in accordance with § 120.11(a)(1)(iv). Monitoring records must include actual measurements (*e.g.*, times and temperatures) in accordance with § 120.8(b)(7), except as exempted by § 120.24. Consequently, verification must include checking the actual measurements that are recorded in the monitoring records. As proposed, the rule has an enforcement mechanism. Specifically, under § 120.9, failure of a juice processor to have and to implement a HACCP system in accordance with part 120 will render the juice products of that processor adulterated under section 402(a)(4) of the act. Penalties for noncompliance are FDA refusing entry to imported products and instituting legal actions such as seizure, multiple seizures, or injunction, against unlawful products or their producers.

(Comment 83) One comment maintained that weekly review of production records is inadequate and suggested that records be reviewed before each batch of product leaves the plant.

FDA disagrees with the comment. The agency stated in the proposed rule that weekly review of HACCP monitoring and corrective action records would provide the industry with the necessary flexibility to move a highly perishable commodity like fresh juice through processing and distribution without interruption, while still facilitating timely feedback of information. FDA notes that the comment provided no information to demonstrate that weekly review of records is inadequate. In fact, weekly record review will quickly indicate whether the HACCP system is out of control on a regular basis, which is a sign that the system is not adequate to assure safety and that revalidation of the system is required. Thus, the agency concludes that weekly review of monitoring and corrective action records is adequate for verification purposes. FDA notes that the requirement for weekly review does not preclude a processor from reviewing

production records on a more frequent basis if the processor wishes to do so.

(Comment 84) One comment suggested that FDA revise § 120.11(a)(1)(iv)(A) to provide for values that are outside critical limits and for which corrective actions are taken (covered in § 120.11(a)(1)(iv)(B)).

The agency disagrees that the requested revision of § 120.11(a)(1)(iv)(A) is necessary because under § 120.11(a)(1)(iv)(B) processors must review records to ensure that the records are complete and to verify that appropriate corrective actions were taken. Therefore, FDA is not making the requested modification.

(Comment 85) Several comments pointed out that the proposed annual validation requirement in § 120.11(b) is not consistent with NACMCF HACCP guidelines. The comments requested that, instead, FDA require validation whenever there are significant process changes or equipment/system failures.

The agency is not persuaded that it should modify the requirement for annual validation. Section 120.11(b) is consistent with the NACMCF HACCP guidelines in that processors must validate their process as needed (Ref. 17). The NACMCF provided as examples whenever there is an unexplained system failure; a significant product, process or packaging change occurs; or new hazards are recognized. FDA has simply defined "as needed" as at least annually or whenever any changes in the process occur that could affect the hazard analysis or alter the HACCP plan in any way. Therefore, FDA is not modifying § 120.11(b) as the comments requested.

(Comment 86) One comment requested that FDA not require a processor to validate the HACCP plan any time changes occur in the prerequisite programs. The comment requested that FDA revise § 120.11(b) to delete this requirement.

The agency agrees with the comment. It is rare that a change in SSOP's will make the HACCP plan ineffective. Validation is not a paper exercise and may be time consuming and expensive. Therefore, FDA is modifying § 120.11(b) to delete the proposed requirement. FDA notes that the final rule requires revalidation when there is any change in the process, including a change in the SSOP's, that decreases the effectiveness of the HACCP plan.

(Comment 87) One comment expressed concern that the proposed validation requirements would have the effect of locking producers into one supplier and that this would stop product development and innovation.

The agency does not agree with the comment. All food processors must take safety considerations into account when contemplating changes in their processes, regardless of whether they are operating under a HACCP system. The agency recognizes that validation could be costly if frequent changes are made in the process that could affect the hazard analysis or alter the HACCP plan and, thus, processors may be reluctant to make changes, even if the changes have the potential to improve the process or the safety of the final product. A change in the supplier of raw ingredients may be a change requiring revalidation. However, a prudent processor will check new suppliers before making any changes to determine that the supplier will not be a source of any safety concerns. Because HACCP systems need to be revalidated only when changes in the process occur that could affect the hazard analysis or alter the HACCP plan in any way, not every change will require revalidation. Similarly, because a hazard analysis needs to be revalidated only when there are process changes that could reasonably be expected to affect whether a food hazard exists, not every process change will require revalidation of the hazard analysis. Therefore, FDA concludes that the requirements of § 120.11(b) and (c) are important for the public safety and will have minimum impact on conscientious processors.

I. Records

The agency proposed that processors maintain records documenting their HACCP system. FDA also proposed general record requirements, and other provisions or requirements dealing with documentation, record retention, official review, public disclosure, and records maintained on computers.

(Comment 88) One comment was concerned that the agency was trying to get access to processors' CGMP records under § 120.12(a)(1) and that this could be a disincentive for companies to keep thorough records.

The agency disagrees with the comment. Section 120.12(a)(1) requires that processors maintain records documenting the implementation of the SSOP's in § 120.6. SSOP'S are select CGMP sanitation requirements that the agency believes are so important to the effective implementation of HACCP that they require separate, specific provisions. The agency believes that the sanitation controls in § 120.6 are of significant importance to the proper implementation of HACCP because sanitation controls, such as controls preventing contamination from pests, have a direct impact on the presence or absence of pathogens during processing, which in turn, directly affects the effectiveness of the HACCP plan. Access to specific SSOP records is important to investigators making reasonable judgements about whether the HACCP plan is working properly. Accordingly, the final rule requires that SSOP records must be maintained and made available during inspections. However, the agency has no intention of requiring, and processors need not make available to FDA, any other CGMP-related records.

(Comment 89) One comment recommended that the agency delete from the regulation any reference to records for end-product or in-process testing. The comment stated that individual processors would keep testing records for FDA review only if it is part of the verification of their HACCP plan.

The agency disagrees that any modification of the regulation is necessary and is not making the requested change. The regulation only requires that end-product or in-process testing records associated with verification of the HACCP plan be available for FDA review and thus, is consistent with the comment. As discussed in section III.L.6, the agency is establishing periodic end-product testing requirements for purposes of process verification of citrus juices that use fruit surface treatment to achieve the 5-log reduction in the pertinent pathogen; processors are required to provide FDA with access to these records.

(Comment 90) One comment stated that a processor with only one location should not have to provide its location on all records, as required in § 120.12(b)(1).

The agency agrees with the comment and is modifying § 120.12(b)(1) to read as follows: "The name of the processor or importer and the location of the processor or importer, if the processor or importer has more than one location."

(Comment 91) Two comments stated that date and time may not be necessary on all records. One comment contended that the date and time are only important on monitoring and corrective action records and, therefore, should only be required on these records.

The agency believes that the date of the activity is important on all HACCP records. The date allows the processor and the FDA investigator to assess whether the record is current, to identify when any deviation occurred, and to track corrective actions. However, the time of an activity is not necessary on records other than

monitoring and corrective action records (*i.e.*, it is not necessary on the hazard analysis or HACCP plan). Therefore, the agency is modifying § 120.12(b)(2) to state that the time of the activity need not be included on records required under § 120.12(a)(2), (a)(3), and (a)(5).

(Comment 92) One comment suggested that there is no need for the hazard analysis to be signed unless there is no HACCP plan because the hazard analysis did not indicate the need for a HACCP plan.

FDA disagrees with the comment. The signature of the most responsible individual onsite at the processing facility or by a higher level official of the company is important for both the hazard analysis and the HACCP plan. The signature reflects the fact that management has reviewed, accepted, and is responsible for the content of the hazard analysis and any resulting plan. Therefore, the agency concludes that both the hazard analysis and any resulting HACCP plan must be signed.

(Comment 93) One comment suggested that the final rule should allow initialing of records instead of a signature, as is done with low acid canned foods.

The agency disagrees with the comment. The food canning establishment registration and the food process filing form for low acid canned foods both require the signature of an authorized individual. Other low acid canned food records must be signed or initialed (§ 113.100). Part 120 has similar requirements for juice product records. Section 120.12(b)(3) states that all records shall include the signature or initials of the person performing the operation or creating the record. However, given their centrality in a HACCP program, it is important that the hazard analysis and the HACCP plan be reviewed and authorized by the most responsible individual onsite at the processing facility or by a higher level official of the processor so as to signify that management of the firm is aware of and has accepted these records (§ 120.12(c)). Therefore, the agency is not modifying part 120 to permit the initialing of the hazard analysis and the HACCP plan.

(Comment 94) One comment argued that consumer complaints often involve quality issues and are primarily handled at headquarters facilities, not processing plants. Therefore, the comment stated that consumer complaint records should not be part of HACCP recordkeeping requirements.

The agency points out that consumer complaint records are not required to be maintained or access given to them under part 120. Processors are required to review consumer complaints as a part of their verification procedures (§ 120.11(a)(1)(i)) to determine whether complaints relate to the performance of the HACCP plan or to reveal previously unidentified hazards. Processors may choose to include consumer complaints in their HACCP records to document verification of the HACCP system, but it is not required.

(Comment 95) One comment stated that the period that records must be held is out of line with product shelf life because fresh juice only lasts 14 days. The comment suggested that records could be kept for 3 months rather than 1 to 2 years.

FDA disagrees with the comment. Some problems, such as trends in the frequency of process deviations, may not be easily recognized in a "snapshot" record review. By reviewing records covering a longer period of time, a processor may be able to identify certain process deviations. Moreover, while it may be true that most fresh products will be unusable within 3 months, some products are processed for longer shelf-life (such as flash pasteurized, refrigerated juices), and retention times of less than 1 year do not provide for sufficient information for the processor's or FDA's verification activities. (See § 120.11(b).) Therefore, FDA has made no changes to § 120.12(d)(1).

(Comment 96) One comment requested that FDA revise § 120.12(d)(1) to read "Subject to part § 120.14, all records required by this part * * *," because there are other importer requirements for recordkeeping outlined in § 120.14.

The agency disagrees with the comment. Section 120.12(d)(1) requires both processors and importers to retain all records required by part 120. Under § 120.12(d)(1), importers must retain the records required under § 120.14 at the importer's place of business in the United States. Therefore, the agency concludes that the modification is not necessary.

(Comment 97) One comment noted that proposed § 120.12(d)(2) requires processors to maintain records related to the adequacy of equipment or processes. The comment stated that if equipment is old or modifications have been made to it, firms may have trouble getting a letter to that effect from the manufacturer. Therefore, the comment stated, scientific studies will have to be performed to determine adequacy, which will be costly, especially for small processors. The comment stated that the requirement is not consistent with parts 113 and 114. It stated that a written communication summarizing requirements to achieve an adequate process would be adequate.

FDA has reevaluated the provision in § 120.12(d)(2) and concludes that it does not afford any additional significant protection to consumers and may add unnecessary burdens for processors. Therefore, the agency is deleting § 120.12(d)(2) and recodifying paragraphs § 120.12(d)(3) and (d)(4) as § 120.12(d)(2) and (d)(3), respectively.

(Comment 98) One comment suggested that FDA restrict recordkeeping requirements to records produced at the manufacturing facility. The comment stated that data used to establish processes should be maintained by the individual or organization that developed the record, not by the processing plant.

FDA disagrees with the comment. It is vital that each processing plant maintain or have access to all records required under part 120, that pertain to products produced by that plant for purposes of both processor review and FDA inspections. The agency has made provision for offsite storage of records, to the extent feasible, to reduce plant storage burden. Specifically, under § 120.12(d)(2), electronic records are considered to be onsite if they are accessible from an onsite location and comply with § 120.12(g). In addition, under § 120.12(d)(2), offsite storage is allowed for certain monitoring records after 6 months following the date that the monitoring occurred as long as the records can be retrieved and provided onsite within 24 hours. Finally, under § 120.12(d)(3), seasonal processors may store records at a reasonably accessible location at the end of the seasonal pack.

Records (such as the hazard analysis, HACCP plans, and verification, including validation, records for products processed in the plant) are needed by both the processor and FDA to determine whether the HACCP system or systems are properly implemented and effective. HACCP systems and associated records may be tailored to each specific processing facility and for different products processed in the facility. Therefore, the agency concludes that all records required by part 120 must be retained at the processing facility to which they relate (or reasonably accessible when offsite storage is permitted) or at the importer's place of business in the United States. As discussed in previous comments, FDA recognizes that processors may review information (*e.g.*, consumer complaints) to develop/evaluate their systems that is not required to be maintained and to which processors are not required to grant FDA

access. Processors may maintain this information at any location that is convenient for the processor.

(Comment 99) One comment pointed out an inconsistency between the preamble to the proposed rule that stated that after 6 months the SSOP and HACCP monitoring and corrective action records could be stored offsite, and the codified language in proposed § 120.12(d)(3) that refers to the storage of SSOP records and the HACCP plan offsite.

FDA agrees that the proposal's preamble and codified were inconsistent. The agency realizes that some juice processors may be required to store records that could require a great deal of space (*e.g.*, the SSOP and HACCP monitoring and corrective action records) and that there may not be adequate storage space in the processing facility for all of these records. However, because of their direct relevance to ensuring safe processing operations at a facility, FDA has concluded that records dealing with the HACCP plan must remain on site for at least 6 months. After that period, such records may be stored off-site if they can be retrieved and returned on-site to the plant within 24 hours so that plant managers and FDA investigators have ready access to the records for use in evaluating the effectiveness of the HACCP plan. Therefore, FDA is modifying § 120.12(d)(2) to refer to paragraphs (a)(1) and (a)(4) instead of (a)(1) and (a)(3).

(Comment 100) One comment requested that FDA delete § 120.12(e) because the agency does not have the statutory authority to see consumer complaints.

The agency advises that consumer complaints are not required records under § 120.12(a) and the rule does not seek to require that FDA be given access to such records. Thus, the agency concludes that no action is necessary in response to this comment.

(Comment 101) Several comments expressed concern about the confidentiality of records associated with an abandoned process. They stated that a manufacturer's processing methods are often considered trade secret even for products that have been abandoned. The comments suggested that the agency make provisions for this in the final rule and handle abandoned product records in the same manner as existing product information. One comment added that current process lines may use technology similar to that used for an abandoned product and that abandoned products may be brought back into production.

The agency advises that the agency intended that proposed § 120.12(f) not permit public disclosure of processing records except where they have been previously disclosed to the public or where they relate to an abandoned product or ingredient and are no longer trade secret or confidential commercial or financial information. FDA acknowledges that the proposal was less than clear as to the status of an abandoned product process. To clarify the final rule, FDA is striking the work "thus" from § 120.12(f) so that the trade secret status of a product process may be maintained by the processor and the information not necessarily subject to public disclosure even though the particular product has been abandoned. The public availability of such information will be evaluated by FDA on a case-by-case basis.

(Comment 102) Several comments requested that HACCP documents in FDA's possession not be made available under the Freedom of Information Act (FOIA).

FOIA provides consumers and others with the opportunity to obtain records in the possession of Federal agencies, including FDA, upon request. There are, however, some restrictions on the types of records available under FOIA. For example, confidential commercial information and trade secrets are exempt from disclosure 5 U.S.C. 552(b)(4). The agency concluded in the seafood HACCP final rule (60 FR 65096 at 65138) (Ref. 62), that HACCP plans, as a general rule, meet the definition of trade secret information, and thus, even if these plans are in agency files, they likely would not be available under FOIA. However, because FDA is bound by FOIA and the agency's implementing regulation in 21 CFR part 20, the agency is unable to exclude categorically all HACCP records in agency files from public disclosure.

J. Training

The agency proposed that only individuals trained in HACCP be responsible for certain key functions in a HACCP system. The agency is correcting an error in § 120.13(a)(3), as proposed, so that the section references § 120.10(b)(5) instead of § 120.10(c)(5) because there is no paragraph (c)(5).

(Comment 103) Several comments requested that FDA provide training for the juice industry.

FDA has limited resources to use for training. Therefore, the agency has no plans at present to provide specific HACCP training for the juice industry. However, the agency is interested in cooperating with States and the industry in the development of training programs. FDA worked with the Seafood Alliance to develop a seafood HACCP curriculum and training courses A similar cooperative effort would be very beneficial in juice processing. Also, the agency is in the process of developing a juice HACCP hazards and controls guide, which will assist juice processors in the development of their HACCP systems.

(Comment 104) One comment questioned whether the agency will acknowledge the equivalency of juice HACCP training, as mentioned in § 120.13(b), offered by other parties (such as a trade association or academic institution) as it did for seafood HACCP. The comment asked how and who would determine training adequacy. Another comment suggested that equivalency of training programs would be better dealt with by establishing training objectives, such as the system used in meat and poultry HACCP, rather than specific materials and curricula.

FDA believes that the development of seafood HACCP training, through the Seafood Alliance, was beneficial for all parties. A basic curriculum was developed, which the agency reviewed, that was available for the industry's use. The agency has encouraged trainers to evaluate their courses against the materials developed by the Alliance and to make modifications necessary to ensure that programs were consistent with and provided at least an equivalent level of instruction to the Alliance course FDA is very interested in cooperating with all interested parties, including academia, consumer groups, and the juice industry, to develop training programs that incorporate the most appropriate objectives and materials. FDA will acknowledge the equivalency of training in the same manner as is done for seafood HACCP.

(Comment 105) One comment argued that criteria for adequate HACCP training should be left up to the States to determine, but did not provide any support for this opinion. The comment also asked that FDA provide States with guidance and funding to carry out HACCP training for existing State personnel and to certify HACCP specialists.

The agency currently intends to provide training to States, through contracts and State partnerships. The agency recognizes that the effectiveness of juice HACCP hinges on consistent implementation and regulation throughout the United States and training, particularly for investigators, plays an important role in such consistency. As noted above, FDA is interested in cooperative work with

States, academia, and industry to develop training programs.

(Comment 106) One comment stated that individual companies should be permitted to determine when experience can substitute for HACCP training. Another comment argued that experience can never substitute for training, although the comment contained no data or other information to support the claim.

FDA believes that in certain circumstances, appropriate job experience can be an adequate substitute for formal HACCP training. FDA is aware that some juice processors have had successful HACCP programs in place for a long period of time and, as a result, employees working with those systems have gained a working knowledge about HACCP that is more than adequate to meet the training requirement. Moreover, FDA's experience is that other segments of the food industry have HACCP programs in place and employee experience gained working with those systems may be transferred successfully to juice processing. It is the responsibility of processors to determine that their HACCP system is functioning appropriately and is in compliance with part 120, a responsibility that includes ensuring that those individuals involved in designing and implementing the HACCP system are qualified.

(Comment 107) One comment suggested that FDA develop a test to determine whether particular job experience can substitute for HACCP training. The comment asked if FDA is developing such a test.

FDA has no plans to develop a test to determine whether job experience can substitute for HACCP training. Job experience that is equivalent to training gained under an adequate standardized HACCP curriculum is certainly one way that individuals may gain the training required in § 120.13(a). However, as noted, it is the responsibility of individual companies to ensure that qualified individuals conduct the hazard analysis and develop the HACCP plan, whether such individual is qualified through training or job experience.

K. Application of Requirements to Imported Products

The agency proposed in § 120.14 specific requirements for importers of juice products because FDA typically does not inspect foreign food establishments. Under § 120.14 of the proposed rule, importers of juice either must ensure that all juice offered for entry into the United States has been processed in compliance with part 120 or import such juice from a country that has an appropriate memorandum of understanding (MOU) with the United States. In addition, importers must maintain records that document the performance and results of the affirmative steps taken to demonstrate compliance with § 120.14.

(Comment 108) Several comments contended that the juice HACCP regulation should not apply to imports. However, other comments disagreed. A few comments suggested that only imported fresh juice be covered, not juices that have been documented to have been thermally processed to meet the 5-log performance standard.

The agency advises that this final rule will cover all imported and domestic fresh or processed juices. First, under the act, all products in interstate commerce, whether imported or domestic, must adhere to the same standards. Moreover, imported juices may have many of the same potential food hazards as domestic products. FDA discussed outbreaks associated with imported juices in the proposed rule (63 FR 20450 at 20450) (Ref. 2), and some of the recent outbreaks discussed in response to comment 26 were associated with imported juice (Refs. 46 and 47). In addition, imported juices may contain food hazards not normally associated with domestic products. The differences in the types of food hazards may be the function of a number of factors, including differences in processing systems and sources of raw ingredients. The fact that HACCP is based on prevention of specific hazards makes it applicable, in general, to food processing wherever the processing occurs. Therefore, the agency agrees with those comments that stated that the rule must apply equally to imported and domestic juice products, because the potential risks are the comparable. The safety of juice must be ensured regardless of where it is produced.

(Comment 109) One comment suggested that FDA clarify the reference to "imported food" in the introductory sentence of § 120.14 to identify that juice is the specifically covered product.

The agency agrees with this suggestion and has revised the introductory sentence of § 120.14 by replacing the word "food" with the word "juice."

L. Process Controls

1. Performance Standard

The agency proposed to require that juice processors, except those that are subject to part 113 or part 114, include in their HACCP plans control measures that will produce at least a 5-log (10^5) reduction in the pertinent microorganism. As proposed, the pertinent microorganism means the pathogen that is likely to occur in juice and that is most resistant to the pathogen reduction technology used and, if it occurs, is likely to be of public health significance. The proposed reduction must be for a period at least as long as the shelf life of the product when stored under normal and moderate abuse conditions.

(Comment 110) Several comments advocated a regulatory scheme of HACCP without the performance standard proposed by FDA. The comments argued that a performance standard is not necessary to ensure the safety of all products (*e.g.*, citrus). Comments stated that requiring a performance standard negates the strength and function of HACCP and indicates that FDA does not trust HACCP alone. The comments asserted that FDA should require either the performance standard or HACCP, but not both.

The agency disagrees that having the performance standard as an integral part of HACCP weakens the HACCP system. As NACMCF has pointed out, the performance standard enhances HACCP by establishing the appropriate level of health protection that must be achieved (Ref. 25). The 5-log reduction performance standard assures public health protection for consumers and assists processors by establishing a minimum microbial standard for safe juice. Particularly for non-heat treated juice, the 5-log reduction requirement provides a standard against which processors can measure the effectiveness of combinations of HACCP controls. Including a performance standard as part of HACCP sets a goal for processors without mandating the means by which they must achieve that goal and also provides a means of determining the equivalence of alternative strategies for controlling pathogens. Finally, FDA disagrees with the suggestion that a performance standard alone will ensure safe juice. As noted previously, there are hazards in addition to microbial contamination, and a performance standard alone does not address the chemical and physical hazards that may be present in juice.

(Comment 111) Many comments stated that the final rule should identify a safety goal instead of a performance standard and let industry decide how to meet it.

FDA points out that the performance standard in § 120.24 is a microbial safety goal and that the final rule allows the industry to decide how to achieve the safety goal. Elsewhere in this

preamble, FDA has included guidance on the application of the 5-log standard, and FDA also intends to issue a juice HACCP hazards and controls guidance. Both of these forms of guidance are available to the juice industry to help in deciding how to achieve the safety goal. Therefore, the agency concludes that no modification is necessary in response to this comment.

(Comment 112) A few comments suggested that producers who do not use dropped fruit should be able to use HACCP without a performance standard. One comment contended that a 5-log reduction is not necessary when the source of the fruit is known and processors follow CGMP's.

This comment did not provide evidence to persuade FDA that using tree-picked fruit, along with HACCP, would make the 5-log performance standard unnecessary. In fact, produce, in general, including tree picked fruit, may not be pathogen free. Agricultural water, birds, insects, and harvesters are vectors that can potentially contaminate produce even though the produce has not come into contact with the ground. Even if pathogens are present on or in the produce used to make juice, processors can make safe juice by attaining the 5-log reduction performance standard.

(Comment 113) Many comments stated that the 5-log performance standard was not appropriate because processors would have to pasteurize their juice to meet the standard. A few comments stated that the 5-log performance standard is unreasonable, counterproductive, and precludes consideration of harvesting and farming practices that help ensure safety.

The agency disagrees with the comments. The performance standard in § 120.24 allows for the use of alternative technologies. The basis for 5-log is discussed in response to comment 124. As noted in section III.L.4, application of 5-log must occur where the treatment has direct contact with any and all pathogens that may be present. For most juices, this will entail direct treatment of the juice after extraction. For citrus juice only, the available data and information show that surface treatments can be used to meet all or part of the performance standard. In either case, treatments should be applied at a single location under the processor's control and immediately before packaging, in order to prevent post-process contamination of the juice. Although fruit producers and juice manufacturers are encouraged to follow GAP's, GAP's such as water and manure management are generally aimed at minimizing the potential for contamination rather than eliminating pathogens that may be present. Thus, use of GAP's would not be a substitute for the 5-log reduction treatment.

(Comment 114) A few comments suggested that, in addition to the 5-log reduction performance standard, producers should be given the option that Food Safety and Inspection Service (FSIS) gives for fermented sausage, which is batch testing to determine that the product contains less than a certain level of pertinent pathogens and then use a 2-log reduction on the batch tested.

FDA disagrees with the comments' suggestion. Juice is significantly different from a fermented meat product in that a fermented meat product is typically inoculated with bacterial cultures as part of the production process. The growth of the added microorganisms modifies the food environment so that pathogenic bacteria are inhibited or inactivated; there is no comparable inoculation and inhibition activity with juice. Moreover, this process occurs over an extended period of time (3 to 6 weeks is common), which allows time for test results to be completed. Juice, especially juice that is minimally processed, must be processed and consumed within a significantly shorter period than fermented products and, thus, extensive microbial testing of finished, processed products is not practical. Therefore, because there is no counterpart in juice processing to the inhibition or inactivation of pathogens by an added bacterial culture, the agency concludes that batch testing to establish that juice contains a minimum level of pertinent pathogens followed by a 2-log reduction in the pertinent pathogen is not an appropriate substitute for the 5-log reduction performance standard.

(Comment 115) Several comments maintained that there are no data to show that certain combinations of preventive steps are not adequate to ensure juice safety. One comment argued that a combination of grading, washing, sanitation, and current extraction techniques are sufficient to meet the 5-log reduction.

FDA is not prohibiting the use of appropriate cumulative controls to attain the 5-log reduction for citrus products. However, as discussed in section III.L.4, FDA has determined that the 5-log reduction must occur where the treatment has direct contact with all pathogens, if they are present. Further, cumulative controls must be completed in a single production facility under the control of the processor, be effective against the pertinent pathogen, be validated, and be vigorously implemented to ensure that the full 5-log reduction is consistently achieved under commercial processing conditions. GAP's and CGMP's that do not meet these criteria would be in addition to, but not count as part of, the 5-log reduction. The agency notes that it is the responsibility of the processor to demonstrate that combinations of preventive steps are adequate to achieve the 5-log pathogen reduction standard.

(Comment 116) A few comments expressed concern that no attention was being given to preventing the presence of pathogens in juice.

Prevention of pathogens in juice is the reason HACCP was proposed and is being finalized. The agency has always taken the position that food safety is enhanced by the use of the highest quality incoming materials. The agency strongly encourages growers to implement preventive controls and has issued GAP guidance to assist growers in the production of safe produce that is not contaminated. FDA is issuing part 120 to assist processors in establishing preventive controls. Specifically, § 120.7(b) provides that the hazard analysis shall include hazards that can be introduced both within and outside the processing plant environment, including hazards that can occur before, during, and after harvest. In addition, § 120.7(d) requires that processors evaluate product ingredients to determine their potential effect on the safety of the finished food.

(Comment 117) One comment requested that FDA explain how the performance standard applies to each different juice (apple, citrus, vegetable, and blends).

FDA advises that the performance standard in § 120.24 applies to all juice, including blends of more than one type of juice. Processes for attaining a 5-log reduction will vary significantly depending on the target pathogen and the type of juice produced. Therefore, it is up to each processor to determine how best to apply the performance standard to its process. FDA intends to develop a juice HACCP hazards and controls guidance for juice that will provide processors information on the application of the performance standard in addition to that provided in this final rule. The scientific literature is another source of information for processors on recent developments to attain the 5-log reduction for various types of fruits and vegetable juices. Guidance documents from State agencies may also provide information.

(Comment 118) One comment suggested that all processors should be required to meet the chosen performance standard the same way.

The agency disagrees with the comment. FDA specifically chose not to mandate that processors use a particular method to meet the performance standard in order to provide flexibility and to encourage innovation. Different methods that have been validated to meet the 5-log reduction standard can be effective in controlling pathogens to the appropriate level, which is the goal of the performance standard. Mandating a specific technology for processors to use would eliminate the incentive for processors to develop new and possibly improved alternative methods. FDA does not want to limit innovative approaches to achieving food safety or the flexibility for processors to choose the most appropriate method for a particular operation.

(Comment 119) Some comments requested a zero tolerance for *E. coli* O157:H7 in juice. One comment was concerned that the NACMCF may have recommended a higher threshold of risk than consumers would consider acceptable. It stated that there is no acceptable level of risk with regards to *E. coli* O157:H7 because it is so virulent that a single organism could be deadly. The comment sought scientific evidence that the 5-log performance standard will truly kill these organisms, as opposed to represent a reasonable number of organisms killed.

The agency disagrees with the comments. FDA notes that no food processing method can be shown scientifically to achieve a "zero" level for a pathogen or any other contaminant potentially present in the processed food due to the detection limits of the relevant analytical methods. For example, the methods used to detect *E. coli* in juice in several State surveys had a detection limit of < 1 cell per 3.33 milliliter (mL) juice. Thus, a negative result does not necessarily mean that the microorganism is not present, just that it is not present at detectable levels. Furthermore, if pathogens are not distributed homogeneously throughout a product, they may be present in the product but not in the sample tested. Conversely, food processing methods can be shown scientifically to reduce, by mathematical increments (*i.e.*, by "logs"), the level of pathogens that may be present in juice and, as a result, to reduce the risk of illness from juice. FDA has received no comments to undermine the assumption based on the NACMCF recommendation that the 5-log performance standard will adequately protect consumers from *E. coli* O157:H7 and other pathogens.

(Comment 120) One comment contended that a 5-log performance standard is unenforceable and that FDA should set pathogen reduction goals similar to those established for meat and poultry.

FDA disagrees that the 5-log performance standard is unenforceable. The reasons FDA did not set a zero tolerance for pathogens, as was done for certain pathogens in meat and poultry, already have been discussed in the response to comment 114. By virtue of the requirements of part 120, FDA believes that the performance standard is enforceable. That is, as part of their HACCP plan, processors must have a validated procedure for achieving a 5-log reduction in the pertinent pathogen for their process and also must have documentation to demonstrate to FDA that the standard is being achieved. Processors who cannot meet these requirements will not be in compliance with part 120 and thus, will be subject to regulatory action.

(Comment 121) A few comments suggested that FDA use "safe harbor" guidelines rather than require the 5-log reduction to ensure juice safety.

The comment did not define the term "safe harbor." FDA assumes, however, that by "safe harbor", the comment means that FDA would provide guidance, such as times and temperatures for thermal treatments, that, if complied with, would be deemed to achieve the 5-log reduction, thus providing a basis to conclude that the processor is in compliance with § 120.24. FDA is currently working with industry to develop guidance on how to achieve the 5-log reduction, and has already met with the apple industry and citrus juice industry to discuss technological options for achieving the performance standard. Although the agency is developing guidance to assist processors in achieving the 5-log reduction, FDA does not intend such guidance to provide a "safe harbor". Thus, juice processors will not be absolved from adopting HACCP and demonstrating through validation and verification that they have met the performance standard.

(Comment 122) One comment noted the statement in the agency's PRIA statement (63 FR 24254 at 24264) (Ref. 6) that other methods of meeting the performance standard may not be as effective as pasteurization or prevent as much illness seems to indicate an agency lack of confidence in methods other than pasteurization.

FDA disagrees with the interpretation of the PRIA statement. The statement referenced from the PRIA reads "To the extent that processors adopt controls for these hazards other than flash pasteurization which are less effective, the percentage of cases prevented may be smaller than those estimated here." The benefits of the rule with regard to illness prevention were developed based on the amount of illness that would be prevented if all juices were pasteurized because, at the time the proposal was published, pasteurization was the primary effective, commercially implemented method for controlling pathogens in juice that had been validated to meet the performance standard. Since the publication of the proposal, it has become evident that there may be methods other than pasteurization, some of which may require FDA approval for their use, that could be used to treat juice (*e.g.*, use of UV irradiation, high pressure). While it is true that pasteurization treatments significantly exceed the 5-log pathogen reduction performance standard, the statement in the PRIA was not intended to imply that methods other than pasteurization are not effective at preventing illness or that these other methods cannot meet the 5-log reduction performance standard.

(Comment 123) One comment noted that pasteurization would add a complicated and unnecessary step to cider production that will take time and require documentation.

FDA is not requiring in this rulemaking that juice be pasteurized. This rulemaking requires that juice be processed under a HACCP system that contains a control or controls that have been validated to achieve a 5-log reduction in the target pathogen. A juice processor may choose to meet the 5-log reduction requirement by pasteurizing product or by any other validated means. Although pasteurization is the primary option available for cider at this time, this final rule does not preclude the development or use of alternative technologies to achieve a 5-log reduction. For example, FDA recently amended the food additive regulations to provide for the safe use of ultraviolet (UV) irradiation to reduce human pathogens and other microorganisms in juice products (65 FR 71056, November 29, 2000) (Ref. 75). Importantly, however, the processor chooses to meet the 5-log reduction requirement, the process utilized by the processor must be validated and verified as achieving a 5-log reduction in the pertinent microorganism. The risks associated with consumption of cider and other juices are well established (see 63 FR 20450 (Ref. 2) and section II.C of this final rule) and justify regulatory requirements that processors establish controls for pathogens and the other hazards associated with juice.

2. Magnitude of Reduction

(Comment 124) Many comments questioned the scientific basis for the 5-log reduction performance standard. A few comments contended that it was too stringent based on actual numbers of ubiquitous coliform bacteria found in cider in State surveys. In support, a survey submitted as part of a comment questioning the basis of a 5-log reduction standard showed that samples of apples in cider mills in Maryland contained an average of only 3-logs of ubiquitous coliform bacteria and no generic *E. coli* or *E. coli* O157:H7. Some comments asserted that a 5-log performance standard is premature considering that the source of *E. coli* O157:H7 contamination in apple juice is not known and suggested that FDA adopt a 3-log performance standard until scientific data are developed to support the need for a 5-log standard. The comments stated that without data to provide baseline numbers for contamination of juice, any performance standard selected might be inappropriately stringent or lax. The comments maintained that the 5-log standard is particularly excessive if a processor is using CGMP's and only uses prime fruit.

Conversely, one comment suggested that the 7-log performance standard used by other high risk food processors would afford more consumer protection. It suggested that the agency compare the protection offered by 5, 6, and 7 log performance standards because *E. coli* keeps proving to be more resistant to controls than previously thought and because a 5-log reduction may not be adequate for all strains of *E. coli*.

FDA discussed the cider survey results in the response to comment 36. In that discussion, the agency noted the limitations of the analytical methods and advised that the survey results did in fact affirm that risk factors such as fecal coliforms, an indicator of the possible presence of pathogens, are present in cider operations and could give rise to microbial food safety hazards in the finished juice.

In establishing the 5-log standard, FDA is relying on the advice of a panel of recognized food safety experts, the NACMCF. In making this recommendation, the Fresh Produce Working Group of the NACMCF considered various situations that could occur with juice (Ref. 63). First, they considered what levels of *E. coli* might typically occur in juice and added a standard 100-fold safety margin. The Working Group then considered a worst case scenario where produce could be contaminated with bovine feces, a source of *E. coli* O157:H7. They determined that a 5-log reduction would both eliminate the *E. coli* O157:H7 contamination and provide a safety margin. In addition to the information factored into determination of the 5-log reduction performance standard, regulatory precedents were considered. The 5-log pathogen reduction performance standard is used by FDA for *Salmonella* inactivation for in-shell egg pasteurization and by FSIS for inactivation of *E. coli* O157:H7 in fermented sausage. The agency has evaluated the NACMCF advice and concluded that the 5-log performance standard recommended by the NACMCF is the most appropriate standard to ensure that juice is safe.

This pathogen reduction performance standard, in combination with the requirement that measurement of the 5-log reduction begins after cleaning and culling of citrus fruits and, for all other juices, when the treatment has direct contact with any pathogens in the juice (discussed in the response to comment 131), provides adequate public health assurance while minimizing the impact of treatments on the sensory attributes of the juices (Ref. 64). While a 3-log reduction could be adequate under certain circumstances, it does not ensure that juice is safe under all circumstances that may occur. In contrast, the 5-log reduction performance standard has a built-in safety factor that provides additional consumer protection.

In light of the comments, FDA has considered a 6- or 7-log reduction standard and concluded this additional level of reduction is not necessary to compensate for possible future microbial resistance. The 5-log reduction refers to numbers of microorganisms, not resistance of microorganisms. Strains of microorganisms may become more resistant to heat, acid, sanitizers or other controls over time. Because microorganisms are capable of developing resistance, it is critical that juice processors periodically verify and validate their process to determine the continued effectiveness of the process. If resistance occurs, processors may need to make appropriate changes in their process so that their process continues to attain a 5-log reduction in pathogens. Therefore, the agency concludes that increasing the performance standard to attain a greater log reduction is not necessary to compensate for possible future increased resistance of pathogens.

(Comment 125) One comment asserted that a 1000-fold safety factor is not consistent with other performance standards set by FDA, although the comment did not reference any specific performance standards. The comment maintained that a performance standard should be based on actual levels of pathogens found in or on fruit plus a 1- or 2-log safety factor.

FDA has concluded that the 5-log performance standard recommended by the NACMCF is the most appropriate standard to assure that juice is safe. In the response to comment 124, FDA discussed how the Fresh Produce Working Group of the NACMCF arrived at the 5-log pathogen reduction performance standard. This performance standard includes the customary 100-fold safety factor, not a 1,000-fold safety factor as asserted by the comment. Therefore, the agency concludes that the 5-log value is consistent with other performance standards set by FDA and, in fact, was arrived at using the 100-fold (2 log) safety factor the comment suggested.

(Comment 126) Several comments stated that 5-log is not an appropriate performance standard for citrus juice because, in trial studies, researchers have not been able to inoculate fruit with sufficient numbers of microorganisms to measure a 5-log reduction. One comment stated that minimum safety performance criteria should be established for citrus because the likelihood of contamination in citrus juices is not high. However, another comment suggested that a 5-log performance standard would be appropriate for orange juice because it can be attained without heat and a 3-log performance standard would be appropriate for apple juice because this may be the maximum attainable without heat treatment.

FDA proposed the 5-log performance standard based on safety considerations and on the recommendation of the NACMCF (Ref. 63). As mentioned in the response to comment 124, while a 3-log reduction could be adequate under certain circumstances to ensure that juice is safe, the 5-log performance standard has a 2-log safety factor that offers additional consumer protection. In addition, the agency found in its review of performance criteria for other foods, that a 5-log reduction in pathogens is the standard for product safety in several cases (Ref. 63). Although the target pathogen may differ among juice types and, thus, change the specific processing parameters (*e.g.*, temperature, processing time) for attaining a 5-log reduction, FDA maintains that the 5-log performance standard is appropriate for all juices. The one area where FDA has data to suggest differences between citrus juice and other juices is with respect to the

potential for pathogen infiltration. Specifically, the available data show that the potential internalization of pathogens in sound, intact citrus fruit is not likely to present a significant public health risk (see the response to 132). Thus, for citrus juice only, the agency has determined that surface treatments may be used to achieve the 5-log reduction standard. Accordingly, citrus juice processors have an additional option in how to achieve the performance standard (*i.e.*, 5-log reduction), but the standard is the same.

FDA also rejects the comment's implicit suggestion that the performance standard should be based on what is technically feasible. In order to assure safe food, a performance standard must be based on safety, not on whether it is attainable using only certain technologies, such as heat treatment. Presenters at the Florida and California FDA workshops on the 5-log pathogen reduction (November 12, 1998 and November 19, 1998) and FDA research presented at the December 8 to 10, 1999, NACMCF meeting demonstrated that researchers could and had inoculated fruit with pathogens to a level that permits measurement of a 5-log reduction. Therefore, FDA is not persuaded that the performance standard should be different for different produce used to make juice.

(Comment 127) Several comments noted that the 5-log performance standard was chosen by NACMCF and that there was no representative of the fresh juice industry on the Committee. The comments maintained that NACMCF may not have considered written comments that were submitted after the public meeting when making its recommendation.

The NACMCF based its recommendation for a 5-log performance standard for juice on safety considerations, which included a scientific evaluation and rationale for a 5-log reduction standard. FDA reviewed the advice from NACMCF and chose to propose the same standard for HACCP systems for juice because the agency determined that the 5-log standard is supported scientifically. The structure of the NACMCF and the way it functions allow for public comment during the meeting, which comments the Committee considers in developing its recommendations. The fresh juice industry presented their views to the NACMCF during the meeting in question. FDA, on the other hand, typically announces a period of time during which comments related to the public NACMCF meeting may be submitted. In reaching its conclusion to propose a 5-log reduction standard, the agency considered written comments, including comments submitted after the meeting, on the appropriateness of the 5-log reduction standard, along with comments presented at the NACMCF meetings and the NACMCF recommendations.

(Comment 128) A few comments requested that FDA not require small producers to meet the 5-log performance standard until alternatives to pasteurization are validated. The comments argued that pasteurization is too costly for small producers.

The agency understands the small processors' concerns. However, the 5-log reduction is based on safety, and therefore, processors must meet the standard in § 120.24, in their HACCP systems in order for public health to be protected. FDA has documented outbreaks that have been attributed to small processors (Ref. 65). In recognition of the circumstances of small processors, however, the agency is establishing staggered compliance dates such that there is an additional 1 year for small processors and an additional 2 years for very small processors to comply with the HACCP final rule. Importantly, such processors must use the label warning statement if they are not processing their product to achieve the 5-log reduction. FDA believes that this approach does not substantially compromise safety and at the same time provides accommodation to small and very small processors. Therefore, the agency declines to modify the regulation to exempt small producers from the 5-log performance standard.

3. Pertinent Pathogens

(Comment 129) Some comments provided views on the types of microorganisms that should be considered the pertinent microorganism for measuring the 5-log reduction. One comment contended that the chosen target organism must make scientific sense based on their extremes of pathogenic viability across multiple reduction steps. A few comments stated that *Listeria monocytogenes* should not be a target pathogen for the performance standard because there is no history of problems with *Listeria* in juice. However, other comments stated that *E. coli* O157:H7 and *L. monocytogenes* are both appropriate target pathogens, especially because *Listeria* contamination is a risk to pregnant women. One comment also stated that *Salmonella* is not an appropriate target microorganism because it is not as acid-resistant as *E. coli* O157:H7.

FDA has concluded that target pathogens must be chosen on the basis of historical association with a product and the way in which the product is processed. For example, there have been apple juice outbreaks associated with *E. coli* O157:H7, *Salmonella* spp., and *Cryptosporidium parvum. Salmonella species* have been associated with outbreaks from orange juice. The NACMCF recommended the use of *E. coli* O157:H7 or *Listeria monocytogenes* as the target organism, as appropriate. This recommendation is based on the number of known outbreaks of *E. coli* O157:H7 in juice and the ubiquitous nature of *L. monocytogenes*. FDA advises that if *L. monocytogenes* becomes a source of outbreaks in the future, especially affecting pregnant women, then processors must consider whether *L. monocytogenes* should serve as the pertinent microorganism for their product.

Processors must also consider the manner in which they are achieving the 5-log reduction and the microbial resistance to the process. For example, a new technology may be effective in attaining a 5-log reduction of *E. coli* O157:H7 in apple juice, but may allow the survival of *Cryptosporidium*. *E. coli* O157:H7 is known to be unusually acid-resistant and *L. monocytogenes* is relatively heat-resistant. The 5-log pathogen reduction standard applies to the most resistant microorganism of concern under the processing conditions used. If the microorganism is resistant to a particular treatment and the treatment does not therefore deliver a 5-log reduction in the microorganism, then, obviously, the 5-log reduction standard has not been met. FDA plans to provide additional information in its Juice HACCP hazards and controls guidance to assist producers in identifying the pertinent microorganism for measuring the 5-log standard.

(Comment 130) Several comments requested that FDA clarify how surrogate microorganisms should be chosen to validate cumulative steps used to achieve a 5-log reduction (*e.g.*, use of sanitizers). One comment requested that FDA require industry to use an agreed upon "cocktail" of surrogates to validate processes.

FDA advises that surrogates should be equally or more resistant to the processing conditions than is the target pathogen to assure that the process also destroys the pathogen. As noted in the response to comment 129, one treatment may be effective in reducing one type of pathogen but have less or no effect on another. FDA will be providing additional guidance on the selection and effective use of surrogate microorganisms for process validation in its juice HACCP hazards and controls guidance. FDA believes that it is the

responsibility of the producer to validate the processes it chooses to use in manufacturing juice products, including determining appropriate surrogate microorganisms. Therefore, FDA is not requiring use of a "cocktail" of surrogates to validate processes.

In choosing and using surrogates, it is important to remember that a cumulative 5-log reduction must be achieved. Therefore, a processor must have evidence that there is a total reduction of 5 logs in the surrogate population and that the same 1- or 2-log reduction is not being counted repeatedly. In other words, if one step reduces the surrogate by 2 logs, the next step must reduce the surrogate by an additional number of microorganisms. In addition, care must be taken that there is no growth of microorganisms between steps.

4. Application of the Performance Standard

(Comment 131) Several comments maintained that, because of the possibility that pathogens may become internalized into fruit (or vegetables), the treatment(s) will need to be applied after the juice has been extracted so that the treatment has intimate (*i.e.*, direct) contact with pathogens. One comment suggested that FDA require at least part of the treatment be applied directly to the juice. Conversely, another comment maintained that, except for warm apples in cold water, the potential for pathogen infiltration is hypothetical. Even then, according to the comment, use of potable water and hygienically maintained tanks could control pathogen internalization despite a temperature differential that could cause water to be pulled into the fruit.

As stated previously, FDA believes that, for all fruits and vegetables, the pathogen reduction control process must begin at the point where the pathogen reduction treatment directly contacts the pathogens. Inherent in the NACMCF recommendation of the 5-log pathogen reduction standard was the assumption that the treatment(s) would be applied in a way that would effectively reduce the entire population of the microorganism of concern by 5-log. In making this recommendation, NACMCF did not contemplate treatments that may eliminate some pathogens while not reaching others, as would be the case for surface treatment of produce susceptible to pathogen internalization. In fact, the NACMCF specifically advised that surface treatments would have little effect on pathogens if they are internalized.

Contrary to the comment, the potential for infiltration is not hypothetical because information and data from the scientific literature demonstrate that, under certain conditions, microorganisms can become internalized. (Refs. 13 and 14) Such internalization may occur through natural plant structures or through decayed or damaged sites on the fruit or vegetable. Water, insects, and birds, all of which may carry human pathogens, can serve as pathogen vectors, resulting in contamination of fruits and vegetables. Internalization may occur before or after harvest although submerging warm harvested fruit in cold water (such as dump tanks and flumes) increases the potential for infiltration into susceptible produce. Similarly, exposing vulnerable external points of fruit or vegetables may also cause water to be taken-up along with pathogens if they are present. Accordingly, for most fruits and vegetables, this means that the pathogen reduction treatment must be applied to the juice after extraction. Moreover, processors should include in their HACCP plans, where appropriate, precautions to avoid or minimize the potential for infiltration (such as by avoiding submerging warm fruit in colder water). In addition, while CGMP's and SSOP's, such as using potable water and sanitary operating conditions during washing, are a base for HACCP, they will not necessarily prevent or correct pathogen infiltration into fruits and vegetables. If pathogens have become internalized in fruit or vegetables, wash treatments, even if conducted consistent with CGMP's, will not eliminate them.

In the case of citrus fruits, FDA considered in the preamble to the proposed rule that the structure of citrus fruits prevented internalization of microorganisms, and thus, for citrus fruits, pathogenic microorganisms are likely to be restricted to the surface of the fruit. As such, FDA tentatively concluded that surface treatments of citrus fruit would satisfy the criterion for direct contact with all pathogens and could, therefore, be counted towards the 5-log reduction standard (see also the response to comment 132).

In response to comments challenging this agency conclusion and in the absence of scientific studies directly on this topic, FDA conducted two studies to determine the validity of its assumption, and made the results available for public comment. The results of one study provided evidence that internalization, survival, and growth of human bacterial pathogens may occur inside oranges. The results of the second study demonstrated that there is uptake of water by oranges and grapefruit when there is a transitory pressure differential between the interior and exterior of the fruit. At the December 1999 NACMCF meeting, FDA asked the NACMCF to consider the potential for internalization of microorganisms by citrus fruits. The NACMCF concluded that it is theoretically possible for microorganisms to internalize in sound, intact citrus fruit under conditions where a temperature differential between fruit and wash water may cause water to be drawn into the fruit. The Committee stated that while this was demonstrated in laboratory conditions, the probability of its actual occurrence under current industry practices was not demonstrated. Accordingly, the NACMCF concluded, based on the available evidence, that the potential internalization and survival of pathogens in sound, intact citrus fruit is not likely to present a significant public health risk.

FDA agrees with the NACMCF conclusion. Importantly, the comments did not provide any data for FDA to conclude otherwise. Thus, the agency is requiring in § 120.24 that the 5-log standard be met by treatments applied directly to the juice, except that citrus juice processors may use treatments to fruit surfaces, provided the 5-log reduction process for citrus begins after cleaning and culling and is accomplished in a single production facility under the control of the processor. (The terms "cleaning" and "culling" are discussed below in the response to comment 132.)

At the present time, FDA believes that only citrus fruits have been demonstrated to be adequately impervious to internal contamination such that it is reasonable to rely on surface treatments of these fruits, and therefore, use of surface treatments to achieve all or part of the required 5-log pathogen reduction is restricted to citrus fruit. Whenever sufficient scientific data are provided to the agency to establish that, for other fruits and vegetables, it is appropriate to begin the 5-log reduction process at other points than the extracted juice or that establish that surface treatment is no longer an acceptable method to contribute to the 5-log reduction for citrus fruit, FDA will review this conclusion.

(Comment 132) A number of comments contained suggestions or asked for clarification about where to start treatment for purposes of calculating the 5-log pathogen reduction. A few comments maintained that processors grading fruit to reduce potential contamination, and processors using other best management practices,

should be able to count these practices towards the 5-log reduction standard. One comment claimed that FDA should allow the measuring of pathogen reduction to begin prior to processing to achieve and count reductions in pathogens from proven sources, such as by cleaning and culling dirty or damaged fruit. Another comment maintained that a 2-log reduction is possible from using tree picked apples instead of drops and that this practice (i.e., excluding drops) should be counted towards achieving the 5-log reduction.

In contrast, several comments stated that the earliest possible point to start counting the 5-log reduction is with clean, sound fruit. One comment maintained that, while overtly damaged fruit carry a greater risk of contamination, apparently sound fruit may also be contaminated and that, therefore, culling is not a screen for microbial contamination.

FDA agrees that food safety is enhanced by the highest quality incoming materials. However, as noted in response to comment 112, FDA does not believe that GAP's (such as using tree picked fruit) or CGMP's (such as washing and culling fruit) are a replacement for the 5-log reduction. Nor can these practices substitute for a portion of the 5-log treatment. Establishment of the 5-log pathogen reduction standard as adequate public health protection was based upon certain starting conditions, including cleaning and culling the produce, and the principal that the pathogen reduction treatment must directly contact the microbiological hazard. As noted, for juice made from fruits and vegetables in which there is a potential for pathogen infiltration, such contact is likely to occur only after the juice has been extracted; for citrus, where pathogen internalization is unlikely under current industry conditions, the 5-log reduction process does not need to start with the extracted juice but may begin with exterior decontamination of fruit after cleaning and culling.

FDA is defining in § 123.3(a) and (f) the terms "cleaned" and "culled" as described by NACMCF to establish the starting point for surface treatments for citrus. *Cleaned* means washed with water of adequate sanitary quality. *Culled* means separation of damaged fruit from undamaged. For processors of citrus juices using treatments to fruit surfaces to comply with § 120.24, *culled* means undamaged, tree-picked fruit (*i.e.*, USDA choice or higher quality). For all juices, cleaning and culling operations would be part of CGMP's, and fruit being tree-picked is not applicable to the 5-log reduction. This is consistent with the NACMCF recommendation that cleaning and culling of citrus fruits not be considered part of the 5-log reduction of pathogens. The agency notes that all produce used for making juice must be cleaned and culled prior to the start of the 5-log reduction according to CGMP's. However, FDA is defining these terms to clearly set forth the basic starting conditions for the 5-log reduction, especially in regard to surface treated citrus.

(*Comment 133*) One comment suggested developing a standard for fruit for juicing that includes no dropped fruit, no blemishes or dimples, and rinsing with pathogen-free water. The comment suggested that beginning with fruit of a standardized quality would not count toward the 5-log reduction, but would ensure that all processors start with fruit of the same high quality. One comment argued that treatments that can achieve a 5-log reduction in pathogens when applied to sound, clean fruit may be adequate for producing safe product but questioned whether a greater reduction might be necessary if starting with fruit that was dirty or damaged.

FDA is not setting a standard for fruit quality or expressly prohibiting the use of drops in most juices. As with any food, FDA encourages the highest possible quality incoming materials in the production of juice. The Produce Working Group of the NACMCF arrived at the 5-log reduction recommendation by considering a "worse case" scenario where fruit was heavily contaminated with feces, as might occur with the use of drops. The Committee concluded that a 5-log reduction treatment would eliminate pathogens and provide a 100-fold safety margin. Thus, FDA concludes that the 5-log reduction applied directly to the juice will eliminate pathogens that may otherwise be introduced by the use of drops. FDA cautions, however, that juice producers that are exempt from or that have not yet adopted HACCP, including the 5-log reduction standard, can reduce their risk of producing contaminated product by avoiding drops and by culling tree picked fruit before extraction.

The agency is establishing a standard for citrus fruit that is treated only with surface treatment. For these juices, drops may not be used. The NACMCF suggested, and FDA agrees, that for citrus juices, only tree-picked fruit should be used, and fruit should be cleaned and culled to be USDA choice or higher quality. Although pathogen infiltration is unlikely in sound, intact citrus fruit, drops and damaged fruit are likely to be more susceptible to pathogen infiltration and, therefore, should not be used for juice that relies on surface treatment.

Furthermore, in some cases, damage incurred when fruit drops to the ground may foster nonmicrobial contamination such as the mycotoxin patulin, which may occur in damaged apples. Patulin, if present in the apples, will not be decreased by the 5-log performance standard. In these cases, the processor must have controls in place to ensure that the final juice does not contain unsafe levels of the mycotoxin.

(*Comment 134*) Several comments urged FDA to define sound fruit. A few comments noted that culling is a subjective process and therefore may not be consistently applied. One comment suggested that the agency establish mandatory common minimum standards and technologies (*e.g.*, black lighting) to ensure consistency in culling operations. Another comment suggested that FDA specify that fruit be culled of unsound fruit before dirty fruit is placed into a flume where it might contaminate sound fruit.

In the case of citrus juice where a surface treatment is used to achieve, at least in part, the 5-log reduction, the agency has specified that the fruit shall be "culled" and "cleaned." As noted, these terms are defined in § 120.3. Fruit and vegetable grading criteria (*e.g.*, for USDA choice level or higher, as will be required for surface treated citrus fruit) have been established by USDA. Although there may be some degree of subjectivity in culling citrus fruit, visibly damaged fruit is apparent and is unlikely to meet the requirements for USDA choice level or higher. Application of CGMP's, along with the 5-log performance standard beginning at a point after cleaning and culling of citrus fruit, should overcome any potential risks that may result from subjective processes such as culling.

As stated in response to comment 132, FDA is not setting a standard for fruit where the juice is treated after extraction to achieve a 5-log reduction, although processors may consider including standards for incoming fruit as appropriate to their operations in establishing a HACCP plan. Additional guidance will be provided in the agency's juice HACCP hazards and controls guidance.

(*Comment 135*) Several comments requested that FDA develop a guide for industry that states the log reduction achieved for each potential processing step. A few comments requested that pasteurization guidelines for juice be published in a guide, and one comment asked whether or not heat treatment at

161 °F for 15 seconds results in the appropriate 5-log reduction in juice. Another comment questioned how to calculate a 5-log reduction for banana juice.

FDA plans to publish a juice HACCP hazards and controls guidance to assist the juice industry in implementing these regulations. FDA intends that the guidance will contain pasteurization guidelines and information about achieving the performance standard in other ways. The agency is unable to comment on whether a heat treatment of 161 °F for 15 seconds results in a 5-log pathogen reduction without information about the characteristics of the juice as well as the thermal resistance characteristics of the pathogen of concern. Appropriate 5-log pathogen reduction treatments for specific juices (such as banana juice) will vary, depending on the characteristics of the juice (*e.g.*, acidity, viscosity, percentage of pulp) and processing conditions. Processors may find it necessary to consult additional resources to determine and implement the most appropriate process to achieve the 5-log pathogen reduction, such as information from State public health or agriculture agencies, universities, extension services, and private consultants. The agency emphasizes that it is the processor's responsibility to validate the chosen pathogen reduction process to assure its effectiveness in consistently achieving a 5-log or greater reduction.

(Comment 136) Many comments expressed confusion about the use of cumulative steps to reach the 5-log pathogen reduction requirement. A few comments also requested that FDA clarify exactly what would be required if two different processors perform steps that in the final product add up to a 5-log reduction. A number of comments stated that separating cumulative pathogen reduction steps by time and or by location is not acceptable. These comments argued that such separation provided opportunities for recontamination of product and regrowth of any existing pathogens that had not yet been eliminated in the product, that any multiple step intervention should take place in a single location, and urged FDA to ensure time between treatments is kept to a minimum once an intervention sequence is begun. Several comments on transporting juice between facilities suggested that FDA require that bulk transport juice (*e.g.*, juice shipped in tanker trucks) be pasteurized upon arrival at the final facility because of the potential for contamination during transport.

FDA agrees with the comments expressing concern about the potential for recontamination or regrowth of surviving pathogens if individual treatments designed to achieve a 5-log reduction are separated by time or space. At the December 8 to 9, 1999, meeting of the NACMCF, FDA asked the Committee to consider certain questions about the application of the 5-log reduction standard, focusing on citrus juices. Questions included the impact of separation in time and space between cumulative steps in the 5-log reduction process. The Committee members agreed that separating steps in the 5-log reduction by time, and especially by location, is likely to increase the risk of failure of the pathogen reduction process (Ref. 12). Thus, the NACMCF recommended that all the steps needed to achieve the required 5-log reduction should occur under one firm's control and within a single production facility. These restrictions are designed to reduce the risk of recontamination of juice already processed to achieve all or part of the 5-log reduction. Both time and the act of transportation, between processors, present an opportunity for recontamination. Even if a processor moves product from one building to another within the same facility, this movement must be accomplished under CGMP's and the processor must insure that recontamination does not occur. As noted, there have been several recent outbreaks of microbially contaminated fresh juice; investigation of these outbreaks establish that the concern about recontamination is not just theoretical because the evidence suggests that transportation may have played a role in these outbreaks. In April 2000, FDA was notified by CDC of a foodborne disease outbreak involving over 140 reported cases from 10 States. CDC determined that the illness was caused by *Salmonella* Enteritidis in unpasteruized orange juice, a component of which had been imported in bulk. Previously, in July 1999, an outbreak of *Salmonella* Serotype Muenchen occurred in 15 States and 2 Canadian provinces with over 300 cases reported. Again, the product was fresh orange juice, a portion of which was imported. In this second outbreak, several serotypes of *Salmonella* were isolated from tanker truckloads of juice tested at the United States/Mexican border (Ref. 67).

FDA agrees with the NACMCF recommendations that all the steps needed to achieve the required 5-log reduction should occur under one firm's control and within a single production facility. Although the NACMCF recommendation focused on citrus juice, based on the comments, FDA believes that this recommendation should be extended to all juices. Because of the potential for contamination at a facility over which the final processor/packager has little or no control and because of the potential for contamination during bulk transport, FDA has concluded that there should not be any carryover from one facility to another of any portion of pathogen reduction that contributes to a total 5-log pathogen reduction. If a treated juice is transported to another facility for final packaging or blending and packaging operations, the entire 5-log reduction must be repeated. To clarify this point, the agency is adding paragraph (c) to § 120.24 to state that processors must complete the 5-log performance standard and final product packaging within a single processing facility under CGMP's.

FDA also notes that, for citrus juice producers relying on surface treatments for the 5-log reduction, the single facility criterion also applies to the requirement that processors start with clean, choice or higher grade fruit. Although some juice processors may receive fruit that has been cleaned and graded at another facility, fruit may require additional cleaning and culling to remove any fruit damaged in storage or transit. It is the responsibility of the final juice processor (*i.e.*, the processor at the location where the 5-log treatment will be applied) to ensure that fruit is clean and of appropriate grade before beginning the 5-log reduction.

Even within a single production facility, time between cumulative steps may provide an opportunity for growth or recontamination. Therefore, processors should include in their HACCP plans controls to protect against regrowth of pathogens between steps (*e.g.*, limiting hold time and/or temperature) and to prevent recontamination of the juice during or after processing (*e.g.*, aseptic handling between steps or between treatment and packaging).

FDA also agrees with the concern expressed by comments on the potential for juice to be contaminated during bulk transport. This is an area of particular concern to the agency because, as mentioned above, bulk transport appears to be a common factor in several recent outbreaks. However, the agency has no information nor was any information submitted by comments that the 5-log reduction standard applied to juice in general would not be sufficient to ensure the safety of juice that is shipped in bulk, provided that the transported juice receive the entire

5-log reduction at the facility where it will be packaged. Therefore, FDA is not requiring at this time that juice shipped in bulk between facilities be subject to additional treatment.

(Comment 137) One comment expressed concern that a cumulative process will be more easily overwhelmed by especially dirty fruit than would a single kill-step process. The comment contended that the risk of contamination in a multi-step process is increased over the risk in a single kill-step process because of the potential that contamination can be introduced between steps. One comment expressed concern that validation studies on a cumulative 5-log reduction cannot account for all variables and, thus, meeting the performance standard cannot be guaranteed.

HACCP principles and this final rule require that a processor validate the HACCP plan for its particular process under commercial operating conditions. This validation requirement exists for plans utilizing both single-step and cumulative pathogen reduction controls. FDA recognizes that within a processing system time delays may occur between stages of the treatment; the processor must take any delays into consideration, establish appropriate controls, and validate the HACCP plan for that system. The 5-log reduction performance standard was established to ensure the safety of juice regardless of the pathogen reduction system chosen or the microbial load of the incoming fruit. Furthermore, as discussed in response to comment 132, citrus juice processors using surface disinfection to achieve all or part of the 5-log reduction must start with cleaned and culled fruit as defined in § 120.3 (a) and (f).

(Comment 138) Several comments maintained that juice should be packaged immediately before or after the intervention treatment. One comment stated that a processor could hold and cool a heat treated product before packaging if sufficient controls were in place to preclude recontamination of the product.

As noted earlier, time between cumulative steps and between application of the 5-log reduction and packaging increases the risk of failure (see response to comment 136). Therefore, to reduce the risk of recontamination, juice should be packaged immediately before or after application of the 5-log pathogen reduction treatment. The potential for recontamination between application of the 5-log reduction treatment and packaging (such as might occur when product is held and cooled) should be considered in the development of the HACCP plan and appropriate controls established that are designed to prevent recontamination. Processors not packaging juice immediately after treatment should have sufficient controls in place (*e.g.*, aseptic equipment) to ensure the safety achieved by the 5-log reduction can be consistently maintained.

(Comment 139) One comment asked if the regulation allowed for the application of 5-log reduction to a juice ingredient at any time (*e.g.*, before or after blending). The comment argued that the juice ingredient used to manufacture dairy beverages usually receives a 5-log treatment by the supplier and that the finished beverage is often pasteurized at the dairy.

Juice that is intended for use in further manufacturing is generally shipped in bulk. As discussed in the response to comment 136, the NACMCF recommended and FDA agrees that if bulk transport juice will be repackaged at another facility, the 5-log reduction process must be performed on the juice at the facility where it is packed into final packages. If treated juice is packaged into a bulk-type sterile package, such as a single use sanitary tote, then reprocessing is not necessary unless it is repackaged. If juice shipped in sterile totes is to be repackaged at a different facility, the juice product sold to consumers must be retreated to attain the 5-log reduction at the facility where final packaging is performed. As discussed earlier, separation in time and location increases the risk of failure of the HACCP system, including the 5-log reduction. Therefore, FDA is not providing for carryover of any part of the 5-log reduction when juice, not in its final packaged form, is transported between two facilities.

Juice destined for use as an ingredient in another juice beverage must also undergo a 5-log reduction process. The processor may choose either to treat the juice ingredients before blending or to treat the final product, so long as the entire 5-log reduction is completed in a single production facility under the control of the processor and the processor minimizes time between treatment and packaging.

(Comment 140) Several comments noted that shelf-stable juices are processed well in excess of the 5-log reduction necessary for pathogen control. The comments requested that FDA exempt shelf-stable juice producers from a CCP for pathogen reduction because the shelf-stability of the product is proof that their process greatly exceeds safety performance criteria. Comments also requested that the same consideration be given to concentrated juices.

The agency agrees with the comments and is providing an exemption from the requirements of § 120.24 for shelf-stable and concentrated juices, under specific conditions. Shelf-stable juice products are generally processed at high temperatures in a single step to destroy spoilage microorganisms and enzymes (Ref. 68). These temperatures far exceed what is needed to attain the 5-log reduction in the pertinent pathogen. Therefore, FDA concludes that it is reasonable to exempt a processor of shelf-stable juices from the requirements of § 120.24, if the firm uses a single thermal processing step to attain shelf-stability.

FDA also recognizes that the production of thermally concentrated juice utilizes thermal treatments similar to those used for the production of shelf-stable juices (Ref. 68). A thermal concentration process generally consists of an initial thermal treatment, similar to that used for shelf-stable juices, followed by several thermal evaporation steps. For this reason, the agency has concluded that when a thermal processing step is used before a thermal evaporation process, the processor should be exempt from the 5-log reduction requirement.

Accordingly, FDA is adding § 120.24(a)(2) exempting juice processors using a single thermal processing step sufficient to achieve shelf-stability of the juice or a thermal concentration process that includes thermal treatment of all ingredients from the requirements of § 120.24 (the 5-log reduction requirement). When completing the written hazard analysis as required by § 120.7, processors of shelf-stable and concentrated products using a thermal treatment need not identify pathogens as a hazard that is reasonably likely to occur. To demonstrate that its process is sufficient for the exemption, a processor must include a copy of the thermal process used to achieve shelf-stability or concentration in its written hazard analysis as required by § 120.7.

Shelf-stable or concentrated juice processors are not exempt from the requirement to conduct a written hazard analysis because of the possibility that chemical or physical hazards may be reasonably likely to occur. However, if, based on its hazard analysis a processor exempt from § 120.24 determines that there are no chemical or physical hazards that are reasonably likely to occur in its juice product, then that processor is not required to have a HACCP plan. Juice processors that do not have a HACCP plan need not

comply with the following provisions of part 120:

- § 120.8, HACCP plan
- § 120.10, Corrective actions
- § 120.11(a) (except paragraph (a)(1)(i)), Verification
- § 120.11(b), Validation of the HACCP plan
- § 120.12(a)(3) and (a)(4), Required records
- § 120.24(a) (except paragraph (a)(2)), Process controls
- § 120.25, Process verification for certain processors

FDA anticipates that, in the future, processors making shelf-stable or concentrated juice may use alternative nonthermal processing technologies. While the control mechanism of these nonthermal technologies may eliminate spoilage microorganisms, the effect on pathogens is uncertain. Therefore, the exemption under § 120.24(a)(2) does not extend to nonthermal processes.

5. Validation of the Performance Standard

(Comment 141) One comment stated that the cost of validating a 5-log reduction procedure would be prohibitive to small producers because the validation studies would have to take place in a pilot plant. Another comment stated that processors should be able to validate procedures and critical control limits based on literature reviews, in-plant experience, recommendations from consultants, and routine testing.

The agency disagrees with the comment that argued that validation would be too expensive for small processors because it would have to take place in a pilot plant. FDA notes that validation studies need not occur in a pilot plant. There are several options available to a processor in validating its 5-log reduction procedure and in establishing critical limits. Although it is preferable to establish limits for CCP's and validate individual processes in a pilot plant or in the processing facility where they will be carried out, FDA recognizes that this may not be feasible for small processors. As suggested by the second comment, many alternatives are available. For example, small processors that use identical procedures for producing juice could validate these processes cooperatively. It is also acceptable to use referenced procedures for achieving a particular log reduction provided a processor can demonstrate that the referenced procedure is being followed exactly (or more stringently), as outlined in the literature, and is effective in the processor's operation. Small producers may also elect to use proven technologies (*e.g.*, thermal treatments) that have been extensively validated, and as such can be readily adopted with minimal need to conduct in depth microbiological validation testing.

FDA was unsure what the second comment meant when referring to "routine testing" as a way to validate HACCP. It may be that the comment was referring to "verification" (*e.g.*, routine testing and monitoring) to ensure that the HACCP plan is functioning correctly, rather than "validation". Verification and validation are further discussed in the following section.

6. Process Verification

(Comment 142) Several comments expressed concern about the effectiveness of cumulative steps in meeting the 5-log reduction. One comment pointed out that the efficacy of a cumulative step process for citrus assumes perfect grading and that the interior of citrus is sterile. The comment stated that perfect grading is not possible because pathogens that may have entered the fruit through a microperforation may not be detected and the fruit could have a contaminated interior. The comment also maintained that no steps in the cumulative process described in the proposed rule were designed to prevent reproduction of pathogens in the juice during storage. A few comments concerned about the effectiveness of cumulative treatments argued that FDA should require end-product testing to verify HACCP for all non-pasteurized juice. One comment advocated continuous testing for unpasteurized juice and periodic testing for pasteurized juice. Conversely, one comment maintained that, in most cases, microbial testing is not necessary nor is it the best method for verifying HACCP. However, this comment suggested that microbial testing be required for citrus juice using surface treatments to achieve 5-log since, according to the comment, there are few other steps that can be used to verify cumulative processes that include surface treatment.

FDA's response to these comments requires an understanding of the differences between two HACCP concepts: validation and verification. Verification includes all activities, except monitoring, that establish the soundness of the HACCP plan and that the system is operating according to the plan. Many verification activities, such as process verification, are an on-going (*e.g.*, daily or weekly) part of operating under a HACCP plan. Validation is a subset of verification activities that occurs when a HACCP plan is first set up and whenever significant changes are made that may have an impact on the effectiveness of the system. Validation focuses on collecting and evaluating scientific and technical information to determine whether the HACCP plan, when properly implemented, will effectively control all hazards that are reasonably likely to occur. In contrast, verification assesses whether the HACCP plan, once established, is working properly.

FDA disagrees that microbiological testing of the final juice should be required of all juice manufacturers. If juice is treated to achieve a 5-log reduction in a target pathogen after the juice is expressed, the extent of the reduction (>100,000-fold) in combination with the low levels of pathogens that have been detected in untreated juice would likely result in a post-treatment level of microorganisms that is too low to be detected using reasonable sampling and analytical methods. Moreover, microorganisms are not likely to be uniformly distributed throughout the juice and, accordingly, may not be present in the sample tested even though they are in the juice. This can result in false negative test results. Determination that the product has been adequately treated is more effectively verified by review of the monitoring records for the appropriate CCP. Thus, as a general rule, FDA is not requiring end product testing as part of verification for processes where the juice itself has been directly treated. The exception to this general rule is that processors of citrus juice that use surface treatments to achieve the 5-log reduction performance standard will be required to conduct end product testing to verify that their HACCP system, including the cumulative step 5-log reduction, is operating as it is designed to operate. This verification testing is discussed in more detail below. Of course, even where not required, processors may elect to use end product testing as part of the verification of the HACCP plan.

Conversely, except for techniques like pasteurization, where industry has a long history and experience of using time-temperature parameters as an indicator of microbial destruction, a processor will likely need to conduct studies using samples inoculated with pathogens (or surrogates) to confirm that their HACCP process does result in a 5-log reduction in the pertinent pathogen.

In light of comments expressing concern about the efficacy of cumulative steps, including surface treatment of cleaned and culled citrus fruit, FDA has evaluated the need for additional forms of process verification for some

products. As noted, verification is designed to demonstrate that the HACCP plan is achieving the level of process control intended and thus producing safe food on a continuing basis. Verification is broader than ongoing process monitoring alone. The purpose of monitoring is to measure and document that those identified steps that must operate within specified limits on a continuing basis in order to control a foodborne hazard (*i.e.*, CCP's) are in fact operating within specifications. Ideally, monitoring involves continuous, "real-time" measurements so that process deviations can be detected and corrected immediately.

Conversely, verification entails both the periodic review of monitoring data and the acquisition of additional data to assess whether the HACCP plan is functioning as intended. The additional data are not necessarily data relating to a CCP, but could be data relating to another step in a process that reflects the effectiveness of a prior CCP(s) (*e.g.*, sampling of citrus fruit surfaces for levels of acid resistant mesophilic aerobic microorganisms after treatment of the fruit with an acidic antimicrobial wash). Furthermore, since verification data are only acquired on a periodic basis, types of analyses that require too much time to be effective means for monitoring CCP's can nevertheless be highly effective tools for verifying a HACCP plan. Verification activities may include review of CCP-monitoring records; collection of either in-line or finished product samples for microbiological, chemical, or physical analysis; and direct observations of monitoring activities and corrective actions. The frequency of verification activities will vary depending on factors such as the type of process, volume of product, the results of prior monitoring and verification activities, and past frequency of process deviations.

As discussed in detail previously, at its December 1999 meeting, the NACMCF considered at length the effectiveness of surface treatment to eliminate microbiological concerns related to citrus fruits. There has been a continuing question of whether the integrity of the outer surface of citrus fruit is sufficiently impervious such that pathogenic microorganisms cannot enter the fruit. If the surface were sufficiently impervious, surface treatments might effectively reduce the risk from microbiological hazards. The NACMCF (1999) concluded that the potential for the uptake and growth of bacterial pathogens such as *Salmonella* Hartford and *E. coli* O157:H7 by intact citrus fruit is unlikely, given current industry practices, and that surface treatment of intact, healthy citrus fruit should adequately reduce microbiological risks. However, the NACMCF also concluded that under certain limited conditions, internalization of pathogenic bacteria is possible. Further, the NACMCF noted that surface treatments of fruits would have little effect on internalized pathogenic microorganisms (Ref. 12). In addition, although the NACMCF concluded internalization of pathogens in sound citrus is unlikely under current industry practices, FDA research confirmed that if a temperature differential exists between the fruit and wash water, washing may cause internalization of pathogens in citrus and other produce through indiscernible punctures of the skin.

The NACMCF observed that while microbiological testing is seldom effective as a means of monitoring a CCP, such testing can play a role in verifying HACCP programs (Ref. 17). Similarly, the International Commission on Microbiological Specifications for Foods (Ref. 69) has recognized microbiological testing of product as one type of HACCP verification.

In relation to HACCP and citrus juice manufacture, the NACMCF (Ref. 12) recommended that periodic microbiological testing of juice be a component of the HACCP verification activities undertaken by those citrus juice manufacturers who rely on surface treatment of fruit to achieve all or part of the microbiological performance standard (5-log reduction).

Because of continuing questions about the possibility of pathogen internalization and because of the lack of alternative verification steps available for processors using cumulative steps, including surface treatments, to achieve the 5-log reduction, FDA concludes that, for citrus juices that rely solely or in part on surface treatments, periodic microbial testing to verify the effectiveness of cumulative processes is integral to the process control verification. Therefore, in § 120.25, FDA is requiring microbial testing for such juice products. This testing is in addition to verification and validation requirements set forth in § 120.11.

(Comment 143) As noted above, several comments argued that FDA should require microbial testing for some or all juices. Some comments favored microbial testing of finished product but did not specify sampling plans or methods. A few comments suggested that FDA could permit companies to test for indicator organisms because *E. coli* O157:H7 is hard to detect. One comment argued that such a requirement would eliminate the need for a HACCP system.

FDA disagrees with the comment that maintained that end product testing would eliminate the need for HACCP for juice. As discussed in response to comment 142, microbial testing is limited in its ability to detect process deviations in a timely manner, especially for products with a short shelf-life, such as fresh juice.

FDA agrees with the comment that suggested that indicator organisms could be used for process verification. While microbiological testing for specific pathogens might be a direct means of verifying that a surface treatment is effective and that pathogens have not been internalized in the fruit, analyses for individual pathogens can be highly complex. Testing for pathogens also has limitations, including the potential for pathogens to be present at low levels compared to other microorganisms and the detection limit of the test. There is also the question of which pathogens that may be present on the surface of the fruit should be the focus of any testing. For example, testing for *Salmonella, E. coli* O157:H7, and *Cryptosporidium parvum* might be appropriate since all three have been implicated in disease outbreaks related to juices. Another limitation of testing for pathogens is that testing for one pathogen (*e.g. Salmonella*) will not detect another (*e.g., E. coli* O157:H7), even if the second pathogen is present. An alternative would be to select a microorganism whose presence is indicative of a loss of process control. Since all three of the pathogens above are fecal in origin, the ideal indicator microorganism would be one that is indicative of fecal contamination.

FDA has considered several different possible indicator microorganisms and has concluded that biotype I *Escherichia coli* (*i.e.*, generic *E. coli*) is the most suitable indicator microorganism for verifying the effectiveness of surface treatments in attaining the 5-log reduction standard. This microorganism is generally regarded by the scientific community as the best indicator microorganism for processes intended to control fecal contamination (Refs. 15 and 70). When present, generic *E. coli* generally occurs at levels several magnitudes greater than the levels of enteric pathogens that are associated with fecal contamination. Consequently, testing for generic *E. coli* is more likely to detect product where the 5-log reduction standard has not been achieved. Thus, FDA concludes that any citrus juice manufacturer that relies solely or in part on surface treatment of

the fruit to achieve the 5-log reduction performance standard shall, for each different type of juice product produced, conduct analyses of the final product for biotype I *Escherichia coli.*

The next issue is how the analysis should be performed. Historically, the juice industry has used the standard 3-tube MPN (most probable number) method in FDA's Bacteriological Analytical Manual (BAM) for analysis of coliform and *E. coli* in juices. However, this method has several limitations. First, as noted in a paper entitled "Derivation of Sampling Plan to Meet the Testing Requirement in the Juice HACCP Final Rule for Citrus Juices That Rely Solely Or in Part on Surface Treatments to Achieve the 5-Log Reduction Standard" ("Surface Treatment Sampling Plan") (Ref. 71), the BAM method can only analyze a small sample size of 3.33 mL with a detection limit of 0.3 *E. coli*/mL. In addition, the high acidity of some juices, including most citrus juices, can interfere with the detection efficiency of the test. Using an analytical method that can test a larger sample size (*i.e.,* 20 mL) and by including an enrichment step to reduce interference by acidity should improve an analysis for generic *E. coli* and thus assist a citrus juice processor using surface treatments to verify whether the process is achieving the 5-log reduction. Consequently, FDA has developed the method, "Analysis for *Escherichia coli* in Juices—Modification of AOAC Official Method 992.30," to detect the presence or absence of *E. coli* in a 20 mL sample of juice (consisting of two 10 mL subsamples) (Ref. 72). In the future, FDA intends to place this method in the BAM. After publication of this final rule, the method will be available on FDA's Internet site at www.cfsan.fda.gov.

In order to facilitate uniform and effective application of this requirement, FDA has added to § 120.25, specific requirements for sample collection and testing. Under this provision, one 20 mL sample, consisting of two 10 mL subsamples, of finished juice shall be analyzed for the presence of generic *E. coli* from each 1,000 gallons of juice produced per day. If less than 1,000 gallons of juice are produced per day, samples must be taken for each 1,000 gallons produced, or once every 5 working days that the facility is producing that juice, whichever comes first. If either 10 mL subsample is positive for *E. coli*, then the 20 mL sample is recorded as being positive for generic *E. coli.*

In addition to the general corrective action requirements in § 120.10, FDA is also adding requirements in § 120.25 to spell out the specific steps that should be taken if a processor subject to the requirements of § 120.25 finds one or more juice samples positive for *E. coli.* Generic *E. coli* is relatively ubiquitous. Thus, the occasional sample that is positive for *E. coli* does not necessarily indicate that microorganisms of fecal origin are not restricted to the surface of the fruit or that surface treatments are insufficient to assure product safety. Nevertheless, an occasional positive sample should prompt a review of the monitoring records relating to the 5-log reduction standard to determine whether pathogen reduction treatments and post process controls designed to prevent re-contamination are being properly delivered. Because generic *E. coli* is an indicator of fecal contamination, processors finding generic *E. coli* in a single sample may consider testing another sample of the same juice for specific pathogens of concern, such as *Salmonella* and *E. coli* O157:H7, to determine whether, in fact, pathogens are present in the juice. FDA is not requiring pathogen testing for the occasional, single positive for *E. coli.* However, if the review of monitoring records or the additional testing shows that the 5-log reduction has not been achieved, such as a sample is found to be positive for the presence of a pathogen or a deviation in the process or its delivery is found, the processor shall take corrective action as set forth in § 120.10 of this final rule. Corrective action requirements for a single positive generic *E. coli* are set forth in 120.25(d).

More than an occasional 20 mL sample positive for generic *E. coli* is an indication that the HACCP process is not sufficient to assure product safety. Under § 120.25, processors relying in whole or in part on surface treatments of the fruit shall have in place a sampling and testing plan sufficient to distinguish between the occasional positive sample and more frequent positives that are indicative of a failure to deliver the 5-log reduction. One way to distinguish between a chance event and an event that results from other factors (such as a failure to deliver the 5-log reduction) is to examine a defined series of tests and assess whether the unusual happens too frequently to be due to chance alone. FDA has evaluated the available data and information, and based on that analysis, has determined that two positives in any series of seven contiguous tests is an appropriate criterion in a sampling plan designed to signal a citrus juice processor relying on surface treatments that its 5-log reduction standard has not been achieved. This standard would alert processors relatively quickly that their system is not delivering the 5-log reduction and, at the same time, would have a relatively small incidence of "false alarms" for processors who are achieving a 5-log reduction. The statistical basis for this criterion is described in the paper entitled "Derivation of Sampling Plan to Meet the Testing Requirement in the Juice HACCP Final Rule for Citrus Juices That Rely Solely Or in Part on Surface Treatments to Achieve the 5-Log Reduction Standard" (Surface Treatment Sampling Plan) (Ref. 71).

FDA acknowledges that there were certain limitations in the data it had available to estimate *E. coli* levels that would be expected in juice not treated to reduce pathogenic microorganisms. For example, available data on *E. coli* levels in citrus juice were limited to orange juice. However, FDA believes that the sampling plan set out in the Surface Treatment Sampling Plan (Ref. 71) can appropriately be applied to all types of citrus juice. Orange juice represents a significant portion of the citrus juice market. For those citrus juices that have a lower occurrence of *E. coli* compared to orange juice, using the same sampling plan will provide an equivalent or greater level of food safety assurance for consumers without increasing any burden, such as the risk of false alarms, for processors. Moreover, a single standard sampling plan will simplify implementation and evaluation of HACCP for citrus juice processors using surface treatments. Other aspects of the data, including its limitations, are discussed in the Surface Treatment Sampling Plan (Ref. 71). FDA believes that the assumptions made, based on its review of available data, were sufficiently sound and reasonable to support this sampling plan. Therefore, FDA is specifying in § 120.25(e) that finding two samples positive for *E. coli* out of a series of seven sequential tests indicates that the 5-log reduction was not achieved. As additional data become available, the agency will consider those data and make adjustments in the HACCP regulation or in the Juice HACCP hazards and controls guide as appropriate.

Under § 120.25(e), if a processor finds two positives out of seven tests, the control measures to achieve the 5-log reduction would no longer be considered adequate. This would require immediate action to ensure that no product enters commerce that was produced where the 5-log reduction was not achieved, because inadequately processed juice creates the potential for the transmission of foodbourne

illnesses. In addition, the processors would need to determine the source of the failure and to take steps to correct the failure. Corrective actions must include a review of the monitoring records for control measures to attain the 5-log reduction standard, and the processor must correct those conditions and practices that are not met. If the review of monitoring records or the additional testing shows that the 5-log reduction has not been achieved, such as a deviation in the process or its delivery, the processor shall take corrective action as set forth in § 120.10 of this final rule. The processor should also review the aspects of the HACCP plan relating to the 5-log reduction standard to determine whether the conditions and practices specified in the plan relating to the 5-log reduction standard are being met. If those conditions and practices are being met, and no other source of the problem can be found (*e.g.*, post process contamination), the processor should conclude that the treatment, although delivered as intended, was not able to achieve the intended 5-log pathogen reduction. In such case, the processor shall revalidate its HACCP plan in relation to the 5-log reduction standard.

While the control measures relating to the 5-log reduction standard are being evaluated, and until all corrective actions have been completed, including, if necessary, revalidation of those aspects of the HACCP plan relating to the 5-log reduction standard, the processor must use an alternative process or processes to achieve the 5-log reduction after the juice has been expressed. Processors should consider why the monitoring and verification results are not in accord, such as through an inadequate process or a failure in process delivery, and whether an alternate approach to achieving the 5-log reduction is needed. Once these steps have been taken, processors may again use the validated approach that relies solely or in part on surface treatments rather than the alternative process.

FDA has concluded that two positive *E. coli* samples in a series of seven tests indicate that the control measures to attain the 5-log reduction standard are inadequate and immediate corrective actions are necessary. Two positives in a window larger than seven tests may be due to chance rather than a failure to deliver the 5-log reduction. However, processors may wish to review test results over a larger window as a possible early warning that the process may be approaching failure. FDA intends to provide additional information in its Juice HACCP hazards and controls guide to assist processors in ensuring their review is sufficiently extensive to determine that no trends towards loss of control are occurring.

The agency concludes that new § 120.25 is a highly effective tool for verifying the 5-log reduction standard for processors using surface treatments. In addition, FDA is modifying § 120.11(a)(1) to include new paragraph (vi) to clarify that the activities in § 120.25 are part of the processor's verification activities.

7. Other Issues

(Comment 144) One comment requested that FDA clarify what is meant by moderate abuse conditions. The comment stated that *E. coli* may be less tolerant under these conditions, so moderate abuse could be a kill step for *E. coli*.

FDA discussed what it considered to be moderate abuse in the proposal (63 FR 20450 at 20478) (Ref. 2). FDA acknowledges that in some circumstances moderate abuse such as slightly elevated temperature in an acidic juice may actually decrease the numbers of certain microorganisms. If a processor intends to use a specific period of elevated holding temperature as a treatment, then the processor must validate the treatment as required for any CCP.

(Comment 145) A few comments asked that FDA eliminate the requirement that the 5-log reduction be maintained throughout shelf-life of the product. The comments maintained that there is no risk of recontamination once the juice is bottled.

FDA agrees that there is little risk of recontamination after a juice is bottled if the container is not damaged and the juice is handled under CGMP's. However, because of the importance of attaining the 5-log reduction for juice to be safe, it is reasonable that juice retain this characteristic throughout the period that it is available for consumption by consumers. Therefore, FDA is not amending § 120.24.

(Comment 146) One comment suggested that the performance standard should be phased in as data on meeting the performance standard becomes available. Another comment suggested that initially, a 3-log reduction could be required, then the following year a 4-log reduction would be required and finally a 5-log reduction.

The agency does not agree. FDA is providing ample opportunity to accommodate processors that may have difficulty implementing the 5-log reduction performance standard. First, the agency has required, since the effective date of the juice labeling final rule, that juice be treated to control pathogens (*i.e.*, meet a 5-log reduction performance standard) or bear a warning label statement. Since that same time, FDA also has been working with the juice industry, through workshops and programs, on the development of techniques that meet the performance standard. Finally, depending on their size, processors will have 1 to 3 years to implement this rule because the agency is providing additional time for small and very small businesses to implement their HACCP systems. Therefore, FDA concludes that it has already provided the means and reasonable time for processors to identify and implement available means to meet the 5-log reduction performance standard.

M. HACCP Enforcement Issues

(Comment 147) One comment requested that FDA establish a preapproval system for HACCP including plant registration, filing of HACCP plans, regular inspections, validation and verification of HACCP plans with microbial testing and tracebacks.

FDA believes that a preapproval system for HACCP plans would unduly burden the agency's resources without substantially increasing public health benefits. The effectiveness of a HACCP plan, including monitoring, recordkeeping, and verification, can best be evaluated under actual operating conditions. Therefore, as part of its enforcement plan for juice HACCP, FDA plans to do inspections of juice processing facilities to ensure compliance with the HACCP regulations after they become effective. These inspections will include collection and analysis of product samples for pathogens and other contaminants.

The agency is putting juice processors on notice that FDA is committed to inspecting all high risk firms annually, even before the effective date of this final rule, and intends to include sample collection and analysis as an integral part of that process. In the agency's view, processors of untreated juices, including firms producing citrus juices using surface treatments, fall into the category of high risk firms.

(Comment 148) One comment stated that tracebacks are very important and the need for information relating to origin of the product was not covered in the proposed rule.

FDA agrees that tracebacks are important and believes that the ability to traceback from a foodborne illness outbreak to the source is critical to controlling the size and duration of the outbreak. The source of an outbreak may

be contaminated raw produce or contamination of product during production and distribution. Processors must implement CGMP's to address raw produce suitability for processing and, if there are hazards that are reasonably likely to occur in raw produce, implement HACCP controls for such hazards. The recordkeeping requirements of this rule mandate that all records include the identity of the product and the production code where appropriate. The purpose of these requirements is to ensure that records maintained under part 120 can be readily linked to a product and to the timeframe in which the product was manufactured. Linking a record to a specific product will be especially important when a product must be isolated or recalled. The information required in § 120.12 will help ensure that, when tracebacks are necessary, they can be carried out efficiently.

(Comment 149) One comment suggested that third party inspections should be done to validate HACCP and the results should be publicized.

FDA encourages such self-regulated programs within industry as third party inspections. Validation of the HACCP plan may be done by any individual, including a third party, that has been trained in accordance with § 120.13. The validity of the HACCP plan will ultimately affect the overall compliance status of firms, as determined through the inspection process. This status is public information.

(Comment 150) One comment suggested that FDA should model its HACCP regulation after that of FSIS with more frequent and less lenient inspections and validation testing.

Differences in the way FDA and FSIS implement their HACCP programs are due to differences in the products being regulated. Also, FSIS's authority and funding provides for the presence of inspectors in meat and poultry plants on a daily basis, whereas FDA's authority and resources do not require or allow for such frequent inspections. FDA, to the extent it is able, will work with juice processors during inspections to properly implement part 120.

(Comment 151) A few comments questioned whether FDA was planning to ask states to enforce the HACCP regulations in light of the agency's limited resources. Another comment stated that the States should verify compliance with any applicable safety regulations.

FDA cannot mandate that a State ensure that a firm is complying with FDA regulations. However, FDA has a long history of working cooperatively with the States to enforce food safety regulations, and the agency hopes to continue these cooperative relationships with States in the context of juice HACCP. FDA notes that some States adopt FDA requirements as their own laws and regulations; with those States, the final rule will effectively be enforced by the States.

(Comment 152) One comment requested that first inspections of HACCP systems be nonregulatory.

The agency recognizes the benefits of a nonregulatory (*i.e.*, educational) first inspection of implementation of a new HACCP system. For the seafood HACCP program, FDA elected to make the first inspection educational, rather than regulatory, as long as there were no urgent public health problems. FDA chose that approach because, for most processors, the first inspection provided the first direct feedback from the agency on the status of the firm's HACCP system. FDA will consider whether the same approach is warranted for some or all juice processors.

(Comment 153) One comment questioned the type of training that FDA would be providing its investigators to ensure that they understand the relevance of microbial data and that they will not go on "witch hunts" to find something wrong with the facility.

FDA's food processor investigators have considerable experience with HACCP in that most are currently conducting seafood HACCP inspections. Investigators are trained to look for violations of FDA regulations and to employ discretion and good judgment (*e.g.*, consider the significance of the violation) in determining how inspectional findings are handled. Further, an investigator's significant inspectional findings are reviewed by multiple higher level FDA employees to confirm the violation prior to the initiation of any regulatory action by the agency.

N. Miscellaneous Issues

(Comment 154) One comment suggested that FDA develop a juice HACCP pilot program.

FDA currently has a HACCP pilot program that includes juice processors. To date, two pasteurized juice processors and one fresh juice processor have completed the HACCP pilot program. FDA has used experience gained from the participation of these juice processors in the HACCP pilot program in proposing and finalizing this rule (Ref. 73).

(Comment 155) Several comments stated that FDA should not impose regulations on industry that will scare consumers into buying only certain foods (i.e., pasteurized juices).

It is not the aim of this rulemaking to scare consumers into buying only certain foods, such as pasteurized juices. However, juices have been the source of a number of outbreaks of illness and the death of one child, as well as have contributed to the death of an elderly man. Juices have also been the source of chemical and physical contaminants that have adverse public health effects, such as high lead levels, the presence of patulin, and the presence of glass pieces. For these reasons, the agency has determined that measures are necessary to ensure that juice is safe and to prevent additional illnesses and deaths, particularly among at risk groups. The primary purpose of this rulemaking is to protect the public, not scare them. FDA believes that these measures will promote public confidence in the safety of juice products.

IV. Effective Date

FDA proposed that any final rule based on the proposal become effective 1 year after its date of publication in the **Federal Register**. Further, FDA proposed that any final rule based on the proposal would not be binding on small businesses as defined in § 120.1(b)(1) until 2 years after publication in the **Federal Register**; and for very small businesses as defined in § 120.1(b)(2), the final rule would not be binding until 3 years after publication in the **Federal Register**.

(Comment 156) Many comments expressed concern that small businesses have the longest time to comply with the rules, even though outbreak data indicate that these producers are most likely responsible for producing contaminated juice.

The agency considered, in the HACCP proposal, the various issues surrounding the need for processors to immediately implement HACCP programs and the need to consider options to minimize the burden of the cost of implementation to small businesses (63 FR 20450 at 20463) (Ref. 2). To address the most immediate concerns (*i.e.*, pathogens) with juice, FDA has since finalized the warning label statement regulation in § 101.17(g) and has engaged in extensive education to alert consumers to the problems of consuming untreated juice. All juice shipped in interstate commerce or made from ingredients shipped in interstate commerce, including that produced by small businesses, that has not been processed to achieve a 5-log reduction in pathogens must be labeled with a warning for consumers (§ 101.17(g)). Thus, even if not produced under a HACCP system, the products of these

small businesses will have some safeguards to protect public health. In addition to the label warning requirement, FDA encourages processors to implement a HACCP system as soon as possible to reduce hazards in juice rather than use the warning label statement. Consequently, the agency has decided to focus initial implementation of HACCP on processors that produce the largest quantity of juice and thus have the potential of affecting the largest number of consumers should contaminated product reach the marketplace.

(Comment 157) Several comments requested that the regulations become effective for all processors 1 year after the rule is finalized and several comments requested that the regulations become effective for all processors 2 years after the rule is finalized.

The agency disagrees with the comments. As noted, FDA considered various options for the implementation of the effective date in the proposed rule. The final rule requires that the bulk of juice produced in the United States will be processed under a HACCP system within 1 year. The agency realizes that it may take longer for small and very small businesses to fully implement HACCP systems and has extended the effective date for one or 2 years, respectively, to give them adequate time to comply.

V. Final Regulatory Impact Analysis

A. Introduction

FDA has examined the impact of this final rule under Executive Order 12866. Executive Order 12866 directs Federal agencies to assess the benefits and costs of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Under the Executive Order, a regulatory action is "significant" if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million; adversely affecting some sector of the economy in a material way; or adversely affecting competition or jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues. FDA finds that this final rule is a significant regulatory action as defined by Executive Order 12866.

The Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: an annual effect on the economy of $100 million; a major increase in costs or prices; significant effects on competition, employment, productivity, or innovation; or significant effects on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the Small Business Regulatory Enforcement Fairness Act, OMB has determined that this final rule is a major rule for the purpose of congressional review.

In addition, FDA has determined that this rule is not a significant rule under the Unfunded Mandates Reform Act of 1995 (UMRA) requiring benefit-cost and other analyses. Under UMRA a significant rule is defined as "a Federal mandate that may result in the expenditure by State, local and tribal governments in the aggregate, or by the private sector, of $100,000,000 (adjusted annually for inflation) in any 1 year".

This Final Regulatory Impact Analysis reflects changes made in the regulation from the proposed rule to the final rule and changes in estimates as a response to comments. It also includes responses to comments on the PRIA. Where there were no changes in the estimates provided in the PRIA, the estimates are summarized here. Interested persons are directed to the text of the PRIA (Ref. 6) for a fuller explanation of the estimates over which there was no controversy or changes. The PRIA discussed a number of regulatory alternatives. FDA received some comments on these alternatives, however, none were specifically economic in nature. Thus, FDA's responses to comments on these alternatives are given in section III.1. There were no specific economic comments on the regulatory alternatives outlined in the PRIA.

B. Factors Considered in Developing This Analysis

This final rule requires all juice processors (as defined in the rule), regardless of size, to implement a HACCP program with a 5-log reduction (that is, a 100,000-fold reduction in pathogens) performance criterion. In the proposed rule, FDA tentatively exempted retailers. In addition, FDA tentatively decided to exempt as retailers very small businesses that make juice on their premises and whose total sales of juice and juice products do not exceed 40,000 gallons per year and who sell directly to consumers and other retailers. Based on the comments and other information, FDA has determined that it is necessary to cover such very small businesses. The estimated benefits and costs for this final rule reflect this change in the coverage of the rule.

Table 1 gives the time to the effective dates by size of firm in terms of time from the date of publication of this final rule.

TABLE 1.—TIME TO EFFECTIVE DATE BY SIZE OF FIRM

Firm size	Time to effective date
Large firms	12 months.
Small firms	24 months.
Very small firms	36 months.

For purposes of this rule, the agency is defining large processors as those who have more than 500 employees, small processors as those who have less than 500 employees and very small processors as those who have: (1) Total annual sales of less than $500,000, or (2) that have total annual sales of greater than $500,000 but total annual food sales of less than $50,000, or (3) that employ fewer than 100 full-time equivalent employees and annually sell less than 100,000 units of the juice in the United States.

This rule follows the implementation of the juice labeling rule, which covers juice that is packaged and has not been subjected to a 5-log reduction treatment. Because the coverage of the juice labeling rule and this juice HACCP rule overlap, and because to some extent both rules address microbial hazards associated with juice, it is necessary to take into account the benefits and costs estimated for juice labeling to avoid double-counting benefits and costs for juice HACCP.

C. Benefits

This analysis provides estimated benefits due to reduced adverse health effects. Presented here is a summary of the analysis provided for the proposed rule. Comments are addressed, and any changes from the analysis for the proposed rule are detailed in each section as appropriate.

FDA uses the following steps to estimate health benefits:

1. The most significant hazards in juice are described in terms of severity and duration;

2. The hazards are described in terms of resulting health effects and symptoms when they cause illness;

3. The health effects and symptoms are translated into consumer utility losses;

4. The utility losses are translated into values in terms of lost dollars (this gives the cost per case for every combination

of level of severity and for the specified duration for each hazard);

5. The average annual number of reported cases associated with juice covered by this final rule are listed;

6. The factors used to account for under reporting of foodborne illness are explained;

7. The estimates of the average annual number of cases are given;

8. The estimated number of cases is divided according to level of severity;

9. The percentages of each type of hazard expected to be prevented by the proposal are listed; and

10. The total health benefits of the proposal are derived by multiplying steps 4, 7, and 8.

That is, TB = RC x CF x CR x V, where

TB = total health benefits in dollars,

RC = number of reported cases,

CF = under reporting correction factor,

CR = percent of cases reduced,

V = dollar value per case averted (medical costs + value of pain and lost function).

One comment stated that FDA had underestimated the amount of untreated juice consumed and, therefore, had underestimated the number of cases of illness associated with juice. FDA disagrees that the cases of illness addressed by the rule have been underestimated due to incorrect consumption estimates. FDA did not estimate the number of illnesses based on consumption. Instead, the agency estimated the number of illnesses by multiplying confirmed illnesses associated with juice by factors accounting for under-reporting of foodborne illness. Thus, FDA does not agree with this comment.

One comment questioned the model used to calculate benefits and asked if it has been "calibrated." The comment did not explain how the word calibrated is used in this case. FDA assumed that it meant to compare the estimates obtained using this model with the actual number of illnesses related to juice. FDA has used this model to calculate benefits for rules involving microbial hazards since 1994. The model is an adaptation of peer-reviewed research on estimating the costs of illness and injury (Ref 74). The model is the best method known to FDA for estimating the benefits of rules involving microbial hazards, and is similar to that used by FSIS for similar rules. Because the actual number of cases of illness is not observable, it is not possible to compare the model's estimates to the actual number of illnesses.

1. Description of Microbial Hazards in Juice

The most significant health risks associated with juice products are those that result from microbial contamination. There are other non-microbial potential hazards related to juice that this rule is designed to control. FDA does not have enough data to quantify benefits for these non-microbial hazards. From 1992 to 1998 the hazards associated with commercially processed, packaged juice produced by nonretail establishments included *Bacillus cereus, Cryptosporidium parvum, E. coli* O157:H7, and *Salmonella* non *typhi*. Most of the information in section C of this document (Benefits) is taken from "Appendix: Preliminary Investigation into the Morbidity and Mortality Associated with the Consumption of Fruit and Vegetable Juices" (Ref. 6, the Appendix). The Appendix includes hazards other than those for which benefits have been estimated in this analysis. The hazards considered in section C of this document are those for which the risk is highest, meaning that they are the most significant in terms of probability of occurrence and/or severity of outcome.

Some comments stated that *C. parvum* should have been included in the estimate of benefits for the HACCP proposal. The comments cite FDA's inclusion of *C. parvum* in the list of hazards in the Appendix. FDA included *C. parvum* as a hazard addressed by the labeling rule but not as a hazard addressed by the proposed HACCP rule. The only documented cases of juice-related *C. parvum* illnesses from commercially produced products from 1992 to 1996 were from juice produced by processors making less than 40,000 gallons per year. Because these processors were included under the retail exemption from the proposed HACCP rule, the proposed HACCP rule would not have addressed the *C. parvum* hazard. Because this final HACCP rule covers all processors regardless of the volume of juice they produce, *C. parvum* is a hazard addressed by this final rule.

2. Description of Health Effects and Symptoms of Microbial Hazards in Juice

In order to quantify the loss (disutility) that individuals experience from becoming ill, the pain, suffering, and mobility loss must be scaled. Individuals who become ill suffer losses of functional status in terms of mobility, ability to do other physical activity, and ability to engage in social activities. Individuals who become ill also experience additional losses from the symptoms of the illness.

One comment stated that symptoms and functional effects associated with some cases are more severe than those described by FDA. FDA agrees with this comment. However, it is equally true that symptoms and functional effects associated with some cases are less severe than those described by FDA. The symptoms and functional effects described by FDA were developed with the assistance of medical doctors at FDA and are those of a typical case for each level of severity for each hazard. Effects vary to a considerable degree across cases of any illness or disease. Such variance is not captured by this analysis. However, FDA believes that the use of typical cases is appropriate for this analysis.

3. Utility Losses From Microbial Hazards in Juice

Decreases in functional status and symptoms and problems associated with illness translate into values of disutility. Utility losses for survivors are derived by multiplying the total disutility per day by the number of days that symptoms of the illness persists. This gives the utility loss for survivors in terms of the number of quality adjusted life days (QALD's) for each case of the categories of severity for each hazard. A QALD is a day of perfect health.

4. Value of Losses From Microbial Hazards in Juice

FDA values a QALD at $630. The value of utility losses for survivors comes from multiplying the number of QALD's lost due to the illness by the value of a QALD. This represents the value of pain and function losses that individuals experience. Additionally, there are the societal costs of medical treatment. These costs are shared generally between insurance companies and individuals. They include all aspects of medical expenses (*e.g.*, physician visits, laboratory tests, prescriptions and therapies, hospital stays). The value of losses per case is the sum of the value of utility losses for survivors and the medical costs for the categories of severity for each hazard.

5. Distribution of the Reported Cases per Year for Microbial Hazards in Juice

The analysis for the proposed rule used the average number of reported cases from 1992 through 1996 for each hazard for the types of products covered by the rule.

Some comments claimed that FDA had miscalculated the benefits of the HACCP proposal by including outbreaks associated with non-commercially

produced juice. Although other parts of the proposed rule and the Appendix refer to outbreaks associated with non-commercially produced juice, the estimate of the benefits of the HACCP rule was based only on outbreaks associated with commercially produced juice.

Some comments stated that FDA had miscalculated the average number of cases per year. These comments used data presented in the Appendix to recalculate the average number of cases per year. The comments were confused because the Appendix lists several outbreaks that were associated with non-commercially produced juice. Because this regulation covers only commercially produced juice, outbreaks associated with non-commercially produced juice were not included in the calculation of the average annual number of cases. Thus, the average annual number of cases was properly calculated.

Tables 2 and 3 should clarify which outbreaks FDA has used in this analysis, and why some outbreaks were not used.

TABLE 2.—JUICE OUTBREAKS (1992 TO 2000) USED TO CALCULATE BENEFITS

Product and year of event	Hazard	Number of cases	Source of data on event
Orange juice, 1994	*B. cereus*	85	FDA recall data.
Orange juice, 1995	*Salmonella spp.*	62	Outbreak data.
Apple juice, 1996	*E. coli* O157:H7	70	Outbreak data.
Apple juice, 1996	*E. coli* O157:H7	14	Outbreak data.
Apple juice, 1996	*C. parvum*	31	Outbreak data.
Apple juice, 1996	*E. coli* O157.H7	1	Pennsylvania State Health Dept.
Orange juice, 1999	*Salmonella muenchen*	423	Outbreak data.
Apple juice, 1999	*E. coli* O157:H7	9	Oklahoma State Health Dept.
Orange juice, 2000	*Salmonella enteritidis*	88	Outbreak data.

TABLE 3.—JUICE OUTBREAKS (1992 TO 2000) NOT USED TO CALCULATE BENEFITS

Product and year of event	Hazard	Number of cases	Source of data on event	Reason not included
Orange juice Mixing Compound, 1992.	*Salmonella agona*	25	FDA recall Data	Orange Julius compound is mixed with juice at the retail location but does not contain juice.
Apple juice, 1993	*C. parvum*	160	Outbreak Data	Juice not made by commercial establishment.
Juice flavored Drinks, 1993.	*C. parvum*	Unknown	FDA recall Data	Approved municipal water supply was contaminated, rule not expected to prevent such occurrences.
Carrot juice, 1993	*Clostridium botulinum*	1	Washington State Health Dept.	Home-made product.
Orange juice, 1993	Unknown	23	Ohio State Health Dept.	Contamination likely caused by consumer.
Watermelon Juice, 1993.	*S. spp.*	18	Florida State Health Dept.	Home-made product.
Apple juice, 1996	*E. coli* 157.H7	6	Outbreak data	Juice not made by Commercial establishment.

Some comments claimed that FDA's analysis had not taken into account the efforts to control hazards made by the industry after the October 1996 outbreak. To estimate the number of illnesses that the proposed rule would prevent, FDA used the most recent 5-year period for which final CDC numbers were available. In the analysis of the proposed rule, FDA did not include 1997 in the estimate of illnesses that the rule would prevent because there was too great of a possibility that illnesses that had actually occurred had not yet been reported. FDA can now add the 1997 to 2000 experience to the 1992 to 1996 experience. By doing so FDA addresses this comments concern. The average number of cases reported per year for each hazard is described in table 4.

TABLE 4.—AVERAGE REPORTED CASES PER YEAR FOR MICROBIAL HAZARDS IN JUICE (1992 TO 2000)

Hazard	Average No. of cases reported per year
B. cereus	2
C. parvum	3
E. coli O157:H7	10
Salmonella (non-typhi)	64

6. Estimates of Factors Needed To Offset Underreporting of Foodborne Illness

It is widely recognized that the total number of foodborne illnesses is much greater than those numbers reported to the CDC. In order to compensate for the rate of underreporting, the number of known cases associated with a hazard (*i.e.*, reported to CDC) is multiplied by factors that are estimated to account for underreporting.

One comment took issue with the underreporting correction factors used by FDA. The comment stated that no underreporting correction factor should ever exceed 100. In the analysis accompanying the proposed rule, FDA used two estimates of underreporting correction factors that have been widely cited on this issue. FDA does not agree that underreporting correction factors should never exceed 100. The appropriate correction factors are those based on the best information available, without any limit created by a predetermined number.

Since the PRIA, CDC has published estimates of foodborne illness; in this final estimate of costs and benefits, FDA

is relying on these recent CDC estimates. The estimates of underreporting correction factors used in the PRIA relied heavily on research that was over 20 years old. In some cases, the research preceded the recognition that *E. coli* O157:H7 was a pathogen. The correction factors based on this research required a significant amount of adaptation, extrapolation and interpolation by FDA. By relying on the recent CDC estimates of foodborne illness to determine correction factors, FDA is reducing its reliance on dated research and its own extrapolations. FDA believes that the estimates of benefits based on CDC estimates of foodborne illness should be more objective.

The underreporting correctiion factors calculated from the CDC reported by Mead et al, show the relationship between estimated total cases and culture-confirmed total cases. The factors are based on surveys estimating the probability that: (1) A person who becomes ill seeks medical care, and (2) the probability that the physician will obtain a stool culture from the person, and (3) the probability that the laboratory will test for the pathogen. The factor for a particular pathogen is the inverse of the multiplicative product of those three probabilities. FDA is relying on the CDC point estimates of the average number of cases per year and the CDC underreporting factor. Because CDC did not provide ranges for these estimates, FDA has insufficient information to probide a range of estimates for the benefits of this rule. FDA's use of a point estimate for the number of illnesses should not, however, be interpreted as implying the absence of uncertainty about these estimates.

For two of the hazards in this analysis, *E. coli* O157:H7 and *Salmonella*, FDA has used correction factors based on the ratio of total estimated cases to active surveillance cases estimated. FDA has used these factors for these hazards because the juice outbreaks for these hazards associated with this rule were discovered through the active surveillance of the FoodNet system. The FoodNet system is designed to identify interstate outbreaks and to more thoroughly discover cases associated with an outbreak.

For *B. cereus* FDA has used a correction factor based on the ratio of total estimated cases to reported outbreak cases. FDA has used this factor for this hazard because the juice outbreaks for this hazard associated with this rule were discovered through the standard outbreak reporting process. *B. cereus* is not a hazard tested for in the FoodNet system, and because of its mild symptoms is very likely to be underreported.

For *C. parvum* FDA has used a correction factor based on the ratio of total estimated cases to 10 percent of the estimated passive surveillance cases. According to CDC, reported outbreak cases account for only 10 percent of the cases accounted for through passive surveillance. FDA has used this factor for *C. parvum* because the juice outbreaks for this hazard associated with this rule were discovered through the standard passive surveillance process. *C. parvum* is not a hazard tested for in the FoodNet system, nor is it on the list of hazards reportable to CDC. Because of its mild symptoms it is very likely to be underreported.

The correction factors used in this analysis are given in table 5.

TABLE 5.—ESTIMATES OF FACTORS NEEDED TO OFFSET UNDERREPORTING OF FOODBORNE ILLNESS

Hazard	Correction factor
B. cereus	380
C. parvum	1,071
E. coli O157:H7	20
Salmonella (non-typhi)	38

7. Estimates of Juice-Associated Cases Per Year

In table 6, FDA has estimated ranges of the likely annual number of cases that occur for each of the four pathogens studied.

TABLE 6.—ESTIMATE OF JUICE-ASSOCIATED CASES COVERED PER YEAR

Hazard	Case
B. cereus	3,420
C. parvum	3,210
E. coli O157:H7	200
Salmonella (non-typhi)	2,430

8. Estimate of Juice-Associated Cases per Year Not Prevented by Labeling Rule

FDA estimated that the juice labeling rule would prevent up to 140 juice-associated illnesses (10 *C. parvum*, 40 *E. coli*, 90 *Salmonella*) as consumers avoid consumption of untreated juice. This HACCP rule will effectively supersede the labeling rule for all those processing establishments covered by the labeling rule. Therefore, once it goes into effect, the HACCP rule will be responsible for prevented juice-related illnesses and not the labeling rule. However, this analysis should attribute to the juice HACCP rule prevention of only those illnesses that would not have been prevented by the juice labeling rule had this rule not superseded it. To estimate the potential benefits of this HACCP final rule, FDA subtracted 140 cases that were estimated to be prevented by the labeling rule (assuming that 16 percent of consumers read the label and do not consume untreated juice) from the estimates provided in table 6. The 16 percent consumer response estimates are the largest estimates of consumer response that FDA has made for the juice labeling rule. Therefore, subtracting the 16 percent consumer response estimates from the estimates of the total number of juice-related illnesses yields the lowest number of illnesses that may be prevented by this juice HACCP final rule. Table 7 gives estimates of the number of juice-related illnesses per year not prevented by the juice labeling rule. The estimates in table 7 come from subtracting the estimated 140 cases prevented by the labeling rule from the estimated cases in table 6.

TABLE 7.—THE ESTIMATED NUMBER OF JUICE-ASSOCIATED CASES NOT PREVENTED BY THE LABELING RULE DIVIDED ACCORDING TO LEVEL OF SEVERITY

Hazard	Severity	Percent	Cases
	Mild	99	3,390
	Moderate	1	30
	Severe	.03	1
B. cereus	Total cases	100	3,421
	Mild	90	2,890
	Moderate	9	290
	Severe	.7	20
	Death	.02	1
C. parvum	Total cases	100	3,200

TABLE 7.—THE ESTIMATED NUMBER OF JUICE-ASSOCIATED CASES NOT PREVENTED BY THE LABELING RULE DIVIDED ACCORDING TO LEVEL OF SEVERITY—Continued

Hazard	Severity	Percent	Cases
	Mild	59	95
	Moderate	38	60
	Severe-acute	3	5
	Severe-chronic	4	10
	Death	.0	0
E. coli O157:H7	Total cases	100	160
	Mild	68	1,590
	Moderate	31	730
	Severe	1	20
	ReA-short term	2	50
	ReA-long term	5	120
	Death	5	120
Salmonella (non typhi)	Total cases	100	2,340

9. Percent of Cases Preventable by HACCP Proposal

Table 8 indicates the percent of cases for each hazard expected to be prevented by the rule. In general, most pathogens will be eliminated when a 5-log treatment is applied. For example, *E. coli* O157:H7, *C. parvum* and *Salmonella* should all be completely eliminated from juice by standard methods of flash pasteurization (in the absence of extraordinarily high counts, detrimental human intervention, or equipment failure). However, hazards associated with *B. cereus* will not necessarily be eliminated by heat treatment. This bacterium forms spores that are more difficult to kill by the usual heat process applied to juice.

In the proposed rule, FDA tentatively exempted certain small retail processors. FDA estimated that the exemption for small retail processors would affect 14 percent of the volume of unpasteurized juice. Therefore, the agency estimated that though pathogen controls may be 100 percent effective in controlling some hazards, such controls would only prevent 86 percent of the cases of illness from these hazards, because of the 14 percent of juice not covered. The final rule covers all processors of juice as defined in the final rule; therefore, controls will affect the full volume of juice made by processors. (Retailers are not covered by this rule. Retailers are those businesses that sell only direct to consumers and include grocery stores, supermarkets, farms, roadside stands, restaurants, and eating places.)

TABLE 8.—PERCENT OF CASES PREVENTABLE BY HACCP PROPOSAL

Hazard	Percent of cases preventable by HAACP proposal
B. cereus	10
C. parvum	100
E. coli O157:H7	100
Salmonella (non typhi)	100

Table 9 indicates the number of cases for each hazard expected to be prevented by the rule.

TABLE 9.—ESTIMATES OF JUICE-ASSOCIATED CASES PER YEAR PREVENTED BY HACCP RULE

Hazard	Severity	Percent of cases	Cases
	Mild	99	340
	Moderate	1	0
	Severe	.3	0
B. cereus	Total case	100	340
	Mild	90	2,890
	Moderate	9	290
	Severe	7	20
	Death	.02	1
C. parvum	Total cases	100	3,200
	Mild	59	95
	Moderate	38	60
	Severe-acute	3	5
	Severe-chronic	4	10
	Death	.08	0
E. coli O157:H7	Total cases	100	160
	Mild	68	1,590
	Moderate	31	730
	Severe	1	20
	ReA–short term	2	50
	ReA–long term	5	120
	Death	.04	1
Salmonella (non typhi)	Total cases	100	2,340

10. Estimates of Annual Benefits for HACCP Proposal

The total benefits for the categories of severity for each hazard are derived by multiplying the number of cases prevented by this rule by the estimates of the value of utility losses and medical costs per case. The sum of those benefits for each hazard is the total benefits of this rule for pathogen control. Table 10 gives the estimate of benefits for each hazard.

TABLE 10.—ESTIMATES OF JUICE-ASSOCIATED CASES PER YEAR PREVENTABLE BY HACCP RULE

Hazard	Severity	Dollars
	Mild	$102,000
B. cereus	Total	102,000
	Mild	5,780,000
	Moderate	1,450,000
	Severe	360,000
	Death	5,000,000
C. parvum	Total	12,590,000
	Mild	190,000
	Moderate	240,000
	Severe-acute	165,000
	Severe-chronic.	12,210,000
E. coli O157:H7.	Total	12,805,000
	Mild	1,590,000
	Moderate	1,460,000
	Severe	320,000
	ReA-short term.	350,000
	ReA-long term.	117,120,000
	Death	5,000,000
Salmonella (non typhi).	Total	$125,840,000

Table 11 presents the estimate of annual benefits based on table 10.

TABLE 11.—ESTIMATES OF ANNUAL MICROBIALLY RELATED BENEFITS FOR HACCP PROPOSAL

Hazard	Dollars
B. cereus	$102,000
C. parvum	12,590,000
E. coli O157:H7	12,805,000
Salmonella (non typhi)	$125,840,000
Total	151,000,000

11. Pesticide Residues

There are two potential benefits associated with the regulation of pesticides: (1) Decreases in cancer and other illness caused by chronic consumption of pesticide residues and, (2) social benefits associated with reductions in the costs of recapturing firm goodwill. FDA cannot quantify the cost savings that will occur because of more vigilant monitoring of pesticide residues by firms under a HACCP rule.

12. Summary of Benefits

Table 12 summarizes the benefits of this rule.

TABLE 12.—BENEFITS OF JUICE HACCP RULE

Type of benefit	Annual value
Reduced illness and death from Controlling pathogens.	$151 million.
Reduced harm from physical and chemical hazards.	Not quantified, effects often long-term and probably small.
Total Quantified Benefits.	$151 million

D. Costs

The costs of these rules have been estimated by multiplying the costs for each proposed requirement on a per-plant basis by the number of plants affected by each requirement. Cost per plant will vary by current practice, product, and size.

1. Coverage

In the proposal, FDA tentatively decided that retailers would include processors that are very small businesses, that make juice on their premises, and that directly sell juice or juice products to consumers and other retailers—provided that retail sales of juice and juice products do not exceed 40,000 gallons per year. As noted, FDA has decided in the final rule not to exclude such processors from the rule's requirements. The final rule covers all processors of juice except those who are retailers. Retailers are those businesses that sell only direct to consumers and include grocery stores, supermarkets, farms, roadside stands, restaurants, and other eating places.

Since FDA published the proposed rule, it collected data showing that 24 percent of very small apple juice processors only sell juice direct to consumers. FDA assumes that the same percentage of very small orange juice processors only sell juice direct to consumers. Therefore, about 380 very small apple and 70 very small orange juice processors are exempted from the rule as retailers.

FDA estimated that 5 percent (about 50 plants) of the 900 plants in the FDA Official Establishment Inventory (OEI) would have implemented HACCP as required by this rule by the effective date of the rule even if FDA had not done this rulemaking. No HACCP costs are attributable to this rule for these plants.

Table 13 shows the estimated number of establishments affected by the rule. These numbers exclude the retailers and the 5 percent of plants already doing HACCP.

TABLE 13.—NUMBER OF PLANTS AFFECTED BY THE RULE

Plant type	Number of establishments affected
Juice manufacturers in the OEI	850
Very small apple juice makers	1,220
Very small orange juice makers	230
Total	2,300

2. Length of Production Period

The agency has assumed that 50 percent of the 850 plants in the OEI plus all of the 1,450 very small juice makers affected by the HACCP rule produce seasonally. Table 14 shows the length of the production period for plants producing seasonally and year round.

TABLE 14.—PLANTS' PRODUCTION PERIOD

	Weeks of operation per year	Hours of operation per day	Number of plants
Seasonal	16	12	1,875
Year Round	52	24	425
Total			2,300

3. Cost Estimates by Requirement

a. HACCP costs.
i. CGMP's (§ 120.5)
ii. Prerequisite Program SOP's (§ 120.6)
iii. Hazard Analysis (§ 120.7)
iv. HACCP Plan (§ 120.8)
v. Corrective Actions (§ 120.10)
vi. Verification and Validation (§ 120.11)
vii. Process Verification for Certain Citrus Processors(§ 120.25)
viii. HACCP Records (§ 120.12)
ix. Training (§ 120.13)
x. Imports and Foreign Processors (§ 120.14)

b. Summary of Costs.

c. Take First Year and Recurring Cost Per Activity.

a. *HACCP costs.*—i. *CGMP's (§ 120.5).* No costs are attributed to this section for this rulemaking. In 1996, only 6 percent of the plants inspected were cited for official action. Thus, an overwhelming majority of firms are complying with part 110. Therefore, there is no additional cost of complying with this provision because plants are already complying with part 110. Therefore, FDA assumed that this rule will have no effect on the enforcement of the CGMP's for juice products.

ii. *Prerequisite program SOP's (§ 120.6).—Developing SOP's.* The cost per plant of developing SOP's is approximately $260. If one half of the 850 domestic plants in the OEI and all of the 1,450 very small juice processors do not currently have SOP's, then they will have to develop them to comply with this regulation. Under these assumptions, the total cost for the industry to develop SOP's is approximately $488,000 ($260 x 1,875 plants).

Implementing sanitation controls with corrections of deviations from SOP's. Based on information from inspection reports, FDA assumes that about 30 percent of all 2,300 covered juice plants (about 690 plants) are likely to have sanitation controls that are insufficiently implemented, but which do not warrant administrative or regulatory action. If it costs each of these 690 plants $500 to implement sanitation controls and to correct deviations from SOP's earlier than they would do otherwise, then the total cost for this requirement is $345,000. Because this cost is discounted, it is added as a one-time expenditure in the total costs.

Monitoring and documenting of SOP's. Table 15 shows the distribution of per plant and total industry costs based on the estimate in table 25 for SOP monitoring and documenting needed to comply with this rule.

TABLE 15.—TOTAL ANNUAL COST OF SOP MONITORING AND DOCUMENTING

	Annual per plant SOP monitoring and documenting cost	Number of plants	Annual SOP monitoring and documenting cost
Seasonal	$100	1,662	$166,000
Year round	340	213	72,000
Totals		1,875	238,000

iii. *Hazard analysis (§ 120.7).* FDA estimates that performing a hazard analysis takes 20 labor hours. At $13 per labor hour the cost of performing a hazard analysis is about $250 per plant. Approximately 2,300 plants will need to perform a hazard analysis to comply with this rule. Therefore, the total cost to perform a hazard analysis is approximately $575,000.

iv. *HACCP plan (§ 120.8)—HACCP plan development.* FDA estimates that developing a HACCP plan takes 60 labor hours. At $13 per labor hour the cost of developing a HACCP plan is about $750 per plant. Only those plants that determine from their hazard analysis that they have hazards that are reasonably likely to occur will have to develop a HACCP plan.

Processors that produce shelf-stable or juice concentrate may conclude after their hazard analysis that they need not include pathogen control in any HACCP plan as required by § 120.24(a), if they include a copy of the thermal process in their written hazard analysis. These processors only need a HACCP plan if they have other hazards that are reasonably likely to occur.

Table 16 shows those processors expected to develop HACCP plans.

Adding the categories of processors that develop HACCP plans yields a total of about 1,560 out of the original 2,300 processors that perform a hazard analysis. This may be a small overestimate because some of the citrus processors that now do not make self-stable products may begin to do so because of this rule. It also may be a small overestimate because of the small potential for overlap among the categories.

TABLE 16.—NUMBER OF PLANTS WITH HACCP PLANS

Processors with pathogen Hazards	1,460
Processors with natural toxin Hazards	20
Processors with pesticide Hazards	80
Total processors with HACCP Plans	1,560

Approximately 1,560 plants will need to develop a HACCP plan at a cost of $750 each to comply with this rule. Therefore, the total cost to develop HACCP plans is approximately $1,170,000.

Pathogen controls. In response to this rule, many processors that are not now heat-treating their products are likely to begin doing so. Processors may choose any lawful means to achieve the required 5-log reduction. However, costs here are estimated for pasteurization as the lowest-cost technology now available.

In the PRIA FDA estimated that costs for initiating pasteurization range from $18,000 for a very small seasonal operation to $35,000 for a larger year round operation. FDA received many comments claiming that the initial cost for initiating pasteurization was $30,000 even for a small operation. Because of the number of comments claiming that the initiation of pasteurization would cost $30,000 for a small operation, FDA has used a range for its estimate of the cost of initiating pasteurization for very small processors.

Of the 2,300 processors covered by the HACCP rule only a portion of these will need to initiate pasteurization. In this final rule, processors of shelf-stable juice and juice concentrate will not need to incur additional costs for the control of pathogens. FDA estimates that this new provision in the final rule applies to about 600 processors (70 percent of the processors listed in the OEI) affected by this rule.

FDA estimates that all but 20 of the rest of the affected processors listed in the OEI (230 plants) and 30 percent of the 1,220 very small apple juice processors (370 plants) are already operating pasteurization equipment. Therefore, 600 plants do not need to implement additional pathogen controls.

For the purpose of this analysis, FDA has concluded that it is unlikely that fresh orange juice processors will have to pasteurize their products to achieve a 5-log reduction when a HACCP program is adopted because of the nature of the fruits, the availability of effective surface treatments and the methods of juice extraction commonly used by industry. However, given the information gained from the December 1999 NACMCF meeting on citrus juice and the several recent outbreaks associated with fresh citrus juice, it is clear that most fresh orange processors will need to incur additional costs to implement effective 5-log pathogen reduction controls. In the PRIA, FDA estimated that costs for these processors were limited to the costs of creating and operating a HACCP system with appropriate monitoring and recordkeeping of the necessary CCP's, not to purchasing pasteurizing equipment. In this final analysis, FDA is estimating costs for fresh orange juice processors to improve pathogen controls. Although the measures to improve such controls will not necessarily be pasteurization, FDA is estimating these costs to be equivalent to the costs for initiating pasteurization. FDA only has cost data for pasteurization which is also the only widely-adopted commerical technology for controlling pathogens in juice. Citrus processors may choose to adopt a technology more expensive that the $18,000 to $30,000 estimated here for the implementation of pasteurization. However, the more expensive technologies would likely be adopted for reasons other than compliance with this rule.

Therefore, 20 affected processors listed in the OEI, 300 very small citrus processors and 850 very small apple juice processors (a total of 1,170 plants) will incur costs to implement additional pathogen controls. Table 17 shows the first year total cost of pathogen control attributable to the HACCP rule.

TABLE 17.—FIRST YEAR COST OF PATHOGEN CONTROL ATTRIBUTABLE TO HACCP PROPOSAL

Processor type	Cost per plant	Number of plants	Total
Very small apple juice processors	$18,000 –$30,000	850	$15,300,000 – 25,500,000
Very small orange juice processors	18,000 –30,000	300	5,400,000 – 9,000,000
Juice processors in the OEI	35,0 00–58,000	20	700,000 – 1,160,000
Total		1,170	21,400,000 – 35,660,000

Pasteurization will require ongoing costs for operation and maintenance. FDA estimates these annual costs for labor, utilities, and materials subsequent to the first year to be $7,000 per year for very small processors and $8,000 per year for processors in the OEI. The total cost of pathogen control in subsequent years is given in table 18.

TABLE 18.—SUBSEQUENT YEAR COST OF PATHOGEN CONTROL ATTRIBUTABLE TO HACCP RULE

Processor type	Cost per plant	Number of plants	Total
Very small apple juice processors	$7,000	850	$5,950,000
Very small orange juice Processors	7 ,000	300	2,100,000
Juice processors in the OEI	8,000	20	160,000
Total		1,170	8,210,000

Other costs are related to processing for pathogen control. The pasteurization of juice causes changes in the characteristics of the products, primarily in terms of texture and taste. Some current consumers of nonheat-treated juice will bear the costs of losing a particular product as well as costs of searching for products with the characteristics that they prefer. Thus, one cost of these regulations is the limited loss of "fresh" juice: that is, juice that is not heat (or otherwise) processed.

Some consumer comments indicated a strong preference for fresh juice; however, although FDA expressly asked for comments on this issue in its November 1999 notice, no comments suggested any means of estimating this cost. FDA has no information on how readily consumers will accept pasteurized juice in the place of fresh juice nor does FDA have any other information that could be used to estimate that cost.

Glass and direct food additive HACCP controls. FDA has not attributed any costs for control of glass or unapproved direct food additives although these potential hazards are among those that are likely to be relevant for juice. The agency believes that even if broken glass is determined to be a hazard to processors packing juice in glass, these processors are already currently implementing every feasible control for this potential hazard in order to limit their liability and to provide consumer protection. Additionally, although approximately 25 percent of the processing plants pack juice in glass containers, this number is diminishing rapidly for economic and safety reasons.

Regarding food additives, many juice products contain food or color additives for the purpose of coloring or extending product shelf life. However the agency

believes that even if unapproved food additives are determined to be a hazard, these processors using direct food additives in juice are already currently implementing sufficient controls for these potential hazards as FDA strictly regulates them.

Natural toxin controls. FDA believes that in most every case processors of domestic apples should be able to control natural toxin hazards such as patulin, by processing controls such as washing and culling. This can be accomplished at no additional cost.

Processors using imported juice concentrate are likely to need to initiate a sampling regime for natural toxins. FDA assumes that the 23 large plants will randomly sample 30 shipments per year at a cost of $150 per sample. The total marginal cost of patulin testing is approximately $104,000 (30 tests x $150/test x 23 firms). Costs per plant are $4,500. If any lots are found positive, costs will be incurred for taking corrective action.

Pesticide controls. FDA believes that all 175 affected plants operated by large firms are currently doing a sufficient amount of sampling and monitoring (or receiving supplier certificates) for pesticides residues. Therefore, FDA assumed that there are no additional costs for large firms to control this potential hazard. This does not mean that FDA believes that no large firms will identify pesticides as a hazard that needs to be controlled under HACCP. Large and small firms are more likely than very small firms to use imported produce, which may not be subjected to as strict controls as U.S. produce in all cases. FDA believes that 10 percent of all large and small firms (80 plants total) will determine that pesticide hazards are reasonably likely to occur. However, FDA believes that all large firms are already sufficiently addressing this issue with present expenditures. FDA made this estimate based on its knowledge of the magnitude of the pesticide problem in juice.

If processors determine that pesticide residues are hazards for their product, then they must run pesticide residue tests to ensure that there are no pesticides either over tolerance or used on products for which there is no tolerance. FDA believes that 10 percent of the shipments received by small processors must be covered by a sampling plan. Sixty-five small plants are believed to cover their shipments with a pesticide-sampling plan. Average cost per plant is estimated to be $1,500. The total annual marginal cost of pesticide testing is approximately $98,000 (10 tests x $150/test x 65 firms).

v. *Corrective actions (§ 120.10).—Corrective action plan.* The development of a corrective action plan for juice products is less expensive than revalidation after each deviation from a CL. FDA estimates that a corrective action plan for juice products can be developed in 4 hours with a cost per plant of approximately $50 (about 4 hours of management time).

All of the plants that develop HACCP plans as a result of this rule will develop corrective action plans to comply with this rule. The total cost for 1,560 plants at $50 each to develop corrective action plans is approximately $78,000.

Corrective actions. Plants operating under HACCP plans will take corrective actions when CL's are exceeded for hazards such as pesticide residues, unacceptable fruit for pathogen controls, and presence of natural toxins. Costs of corrective actions are expected to decline as processors gain more experience under a HACCP system and as the number of corrective actions decreases. Tables 19 and 20 show the estimated first year and subsequent year costs of corrective actions per plant.

TABLE 19.—COST OF FIRST YEAR CORRECTIVE ACTIONS

Plant type	Cost per plant	Number of plants	Total cost
Seasonal	$450	1,490	$671,000
Year round	1,460	70	102,000
Totals		1,560	773,000

TABLE 20.—COST OF SUBSEQUENT YEAR CORRECTIVE ACTIONS

Plant type	Cost per plant	Number of plants	Total cost
Seasonal	$110	1,490	$164,000
Year round	340	70	24,000
Totals		1,560	188,000

Verification and validation (§ 120.11).—Verification. The record verification cost per plant per production cycle is given in table 21.

TABLE 21.—COST OF RECORD VERIFICATION

Plant type	Cost per plant	Number of plants	Total cost
Seasonal	$420	1,490	$626,000
Year Round	1,350	70	95,000
Totals		1,560	721,000

Validation. Processors with HACCP plans must validate their HACCP plans during the first year after implementation and at least annually, or whenever any changes occur that could affect or alter the hazard analysis, or

HACCP plan. Further, processors who have no HACCP plans because there are no hazards that are reasonably likely to occur in that process (as may be the case with processors of shelf-stable or concentrated juice), the processor must reassess their hazard analysis when any significant change occurs. Examples of things that may change include: (1) Raw material specifications or sources of raw materials, (2) product formulation, (3) processing methods or systems, (4) packaging, (5) finished product distribution systems, or (6) intended consumers or use by consumers.

Tables 22 and 23 give the estimated cost for validation in the first and subsequent years.

TABLE 22.—COST OF FIRST YEAR VALIDATION

Plant type	Number of validations	Cost per validation	Number of plants	Total cost
Seasonal Small Business	1	$1,000	1 ,640	$1,640,000
Year Round Business	2	1,000	120	240,000
Year Round Small Shelf-Stable or Concentrate Business	1	1,000	130	130,000
Year Round Large Business	2	600	80	96,00 0
Year Round Large Shelf-Stable or Concentrate Business	1	600	95	57,000
Totals	2,265	....	2,065	$2,163,000

TABLE 23.—COST OF SUBSEQUENT YEAR VALIDATION

Plant type	Number of validations	Cost per validation	Number of plants	Total cost
Seasonal Small Business	1	$1,000	1 ,490	$1,490,000
Year Round Small Business	2	1,000	35	70 ,000
Year Round Large Business	2	600	35	42,00 0
Totals	1,630	....	1,560	1,602,000

vii. *Process verification for certain citrus processors (§ 120.25).* Citrus processors that decide to rely on surface treatments of the fruit to achieve the requisite 5-log reduction (rather than treating the juice directly) are required to sample their final product to verify the effectiveness of the HACCP plan. These processors are required to test two 10 mL subsamples for generic *E. coli* every 1,000 gallons or every 5 days whichever is more frequent. FDA assumes that the cost of testing two 10 mL subsamples for generic *E. coli* is $50. FDA estimates that there are 240 citrus processors that will be affected by this section. To estimate the number of samples, FDA began with the estimated annual U.S. untreated orange juice consumption estimate of 11,700,000 gallons. FDA then assumed that 10 million gallons were packaged for resale and therefore covered by this rule. FDA then assumed that the 180 processors that would sample at a frequency of once every 5 days on average process 750 gallons during that time. These processors are assumed to be seasonal processors operating for only 16 weeks a year. FDA made these assumptions based on its knowledge of microbial testing and beliefs about the volume of untreated packaged juice sold by small processors. That set of processors accounts for 2,160,000 gallons annually. The remaining 60 processors share production of the remaining 7,840,000 gallons resulting in about 130 samples per year per processor.

Table 24 shows the estimated cost for process verification sampling for these citrus processors.

TABLE 24.—ESTIMATED COST FOR VERIFICATION SAMPLING

Sample frequency	Number of samples	Number of processors	Cost per sample cost	Total
Every 5 days	16	180	$50	$144,000
Every 1,000 Gallons	130	6 0	50	390,000
Total	10,720	240	.....	$534,000

Also, any time that 2 process-verification samples test positive for generic *E. coli* in a series of 7 samples there is a process verification failure. The processor must not sell the product without further processing and must review its monitoring records, reevaluate its HACCP plan, and if no obvious deficiencies in the HACCP plan are discovered, must revalidate its HACCP plan. FDA estimates that even if all citrus processors that rely on surface treatments to achieve a 5-log reduction are fully successful in achieving the 5-log reduction, 2 samples in a series of 7 will test positive for generic *E. coli* once in every 1,000 samples. Based on an estimate of 10,720 samples taken per year, this will occur about 11 times per year. FDA assumes that the cost of further processing of the product will be more expensive than withdrawing and destroying the product, which should not exceed 1,000 gallons. FDA assumes that the cost of withdrawing and destroying the product plus the cost of reviewing monitoring records, reevaluating and revalidating HACCP plan is $20,000. FDA made this assumption based on its experience with such small lot market withdrawls. Therefore, the additional cost of a process verification failure is $220,000 per year. The annualized cost of a process verification failure is $320 for a seasonal processor sampling every 5

days ((16/1,000) × $20,000 = $320) and $2,600 for a year round processor sampling every 1,000 gallons ((130/1,000) × $20,000 = $2,600).

The total cost of process verification testing for untreated citrus juice is $764,000 per year ($534,000 + $220,000 = $764,000).

viii. *HACCP records (§ 120.12).—Monitoring and recordkeeping.* The additional monitoring and recordkeeping that needs to be done throughout the entire plant is estimated to be equivalent to 5 percent of one worker's time (3 minutes per hour of operation per plant). Table 25 shows the annual cost of additional monitoring and recordkeeping per plant. It also shows the distribution of per plant costs and total industry costs for the additional monitoring and recordkeeping needed to comply with this final rule.

TABLE 25.—COST OF MONITORING AND RECORDKEEPING

Plant type	Cost per plant	Number of plants	Total cost
Seasonal	$900	1,490	$1,341,000
Year Round	5,600	70	392,000
Totals		1,560	$1,733,000

Record maintenance and storage. The annual cost of record maintenance and storage per plant is described in table 26.

TABLE 26.—COST OF RECORD MAINTENANCE

Plant type	Cost per plant	Number of plants	Total cost
Seasonal	$360	1,490	$536,000
Year Round	830	70	58,000
Totals		1,560	$694,000

ix. *Training (§ 120.13).—HACCP coordinator training.* Processors may need to employ a HACCP coordinator to carry out the duties specified for such a person. FDA estimates that the cost of HACCP coordinator training is $1,300 for each of the 2,300 processing plants, or a total industry cost of $2,990,000.

Employee training in HACCP. Each processor with a HACCP plan will need to train employees in their HACCP-related activities. This analysis assumes that each plant must train 5 employees or 10 percent of their employees in HACCP-related responsibilities, whichever is greater. Table 27 describes the cost of training each employee for 8 hours annually (the equivalent of 40 minutes per month for 10 percent of the employees) and the total cost of this level of training.

TABLE 27.—COST OF EMPLOYEE TRAINING

Average plant employment	Number of employees trained	Cost per employee	Number of plants	Total cost
3	3	$100	1,459	$437,700
7	5	100	10	5,000
15	5	100	19	9,500
35	5	100	28	14,000
75	8	100	29	23,200
175	16	100	15	27,000
Totals	5,160		1,560	$516,000

x. *Imports and foreign processors (§ 120.14).—Importers.* The agency estimates that the cost of these activities will be $10,000 for each of the 120 importers in the first year, decreasing to $5,000 in subsequent years. Total costs for importers is $1,200,000 in the first year and $600,000 in subsequent years.

Foreign juice processors. The estimated first year cost per foreign juice exporter is approximately $26,000, and the cost in subsequent years is $22,000. Therefore the total cost in the first year for 300 foreign processors is approximately $8 million and approximately $7 million in subsequent years. Tables 33 and 34 in the Regulatory Flexibility Analysis, which follows, shows typical costs for large plants that have not already implemented HACCP. The agency assumes that these costs are representative of foreign plants exporting to the United States.

b. *Summary of Costs*—The total quantified costs are approximately $44 to $58 million in the first year and $23 million in all subsequent years. Table 28 summarizes costs of the rule by provision.

C. TABLE 28.—TOTAL FIRST YEAR AND RECURRING COST PER ACTIVITY

Activity	First year costs	Recurring costs
Develop SOP's	$488,000	
Prerequisite Program SOP's	345,000	
Monitoring and Documenting for SOP	238,000	238,000
Hazard analysis	575,000	
HACCP plan	1,170,000	
Pathogen controls	21,400,000–35,660,000	8,210,000
Natural toxin controls	104,000	104,000
Pesticide controls	98,000	98,000
Corrective action plan	78,000	
Corrective actions	773,000	188,000
Verification	721,000	721,000
Validation	2,163,000	1,602,000
Process verification	764,000	764,000
HACCP monitoring and recordkeeping	1,733,000	1,733,000
Record maintenance and storage	694,000	694,000
HACCP coordinator training	2,990,000	
Employee training	516,000	516,000
Importers	1,200,000	600,000
Foreign processors	8,000,000	7,000,000
Totals	44,000,000–58,000,000	23,000,000

E. Summary of Benefits and Costs

FDA has examined the benefits and costs of this rule as required under Executive Order 12866. Over time, the relationship between benefits and costs changes, so that, to compare them properly, benefits and costs must be discounted to the present year (the time at which the decisions are being made). The quantified benefits (discounted annually over an infinite time horizon at 7 percent) are expected to be about $2 billion ($151 million/7 percent) and the quantified costs (discounted annually over an infinite time horizon at 7 percent) are expected to be about $400 million.

VI. Regulatory Flexibility Analysis

FDA has examined the impact of this rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant impact on a substantial number of small entities, the RFA requires agencies to analyze options that would minimize the economic impact of that rule on small entities. The agency acknowledges that this rule is likely to have a significant impact on a substantial number of small entities.

A. Objectives

The RFA requires a succinct statement of the purpose and objectives of any rule that will have a significant impact on a substantial number of small entities. The HACCP rule is being issued to ensure that juice processors control all physical, chemical, and microbial hazards in their products.

B. Definition of Small Business and Number of Small Businesses Affected

The RFA requires a statement of the definition of small business used in the analysis and a description of the number of small entities affected.

Table 29 shows the definition of small business for each type of establishment affected and a description of the number of small entities affected by the rule. The agency has accepted the Small Business Administration (SBA) definitions of small business for this analysis.

TABLE 29.—APPROXIMATE NUMBER OF SMALL PLANTS COVERED BY THESE RULES

Type of establishment	North American industry classification system codes	SBA definition of small by category	Category defined as small by SBA	Percent of No. of small businesses covered
Juice manufacturers in the OEI	311421, 311411	Less than 500 employees	75%	675
Roadside-type apple juice Makers	311421, 311411	Less than 500 employees	100%	1,220
Roadside orange juice Makers	311421, 311411	Less than 500 employees	100%	230
Totals				2,125

C. Description of the Impact on Small Entities

1. Costs to Small Entities

Because there is a broad distribution of products covered, firm types, current processing practices and sizes, it would be misleading to report average per firm costs. However, some idea of the costs can be gained from the following examples. The impacts that the costs will have on a firm will vary depending on the total revenue derived from juice by a firm and the profit (return on sales) associated with juice production. Data on food manufacturing firms indicates that 75 percent of firms have return on sales of less than 5 percent.

The first example (table 30) is of a small seasonal apple cider plant that is now producing nonheat-treated juice, with fruit from a known source, and that has not developed or implemented sanitation SOP's. This plant will need to buy a pasteurizer (or find and validate a different process that achieves a 5-log reduction). The next example (table 31)

is a small plant that is producing orange juice concentrate year round with fruit from a known source, and that has already developed and implemented sanitation SOP's (except that records have not been kept on SOP's). The third example (table 32) is a small plant operating year round producing unpasteurized orange juice, using commingled fruit, and that has not developed or implemented sanitation SOP's.

These three illustrative small plants can be compared to two illustrative large plants. The first large plant (table 33) is a large shelf-stable apple juice plant with many employees that operates year round and that imports some apples and therefore must test for patulin, and has not developed or implemented sanitation SOP's. The second large plant (table 34) is a large shelf-stable tomato juice processor using fruit from a known source and with sanitation SOP's fully implemented.

TABLE 30.—COSTS FOR ILLUSTRATIVE SMALL SEASONAL APPLE CIDER PROCESSOR

Type of cost	Cost in first year	Cost in subsequent years
Develop SOP's	$260	
Sanitation SOP's	500	
Monitoring and Documenting of SOP 's	100	$100
Hazard analysis	250	
HACCP plan	750	
Pathogen controls	18,000–30,000	7,900
Corrective action plan	50	
Corrective actions	450	110
Verification	420	420
Validation	1,000	500
HACCP monitoring and recordkeeping	900	900
Record maintenance & storage	360	360
Training of coordinator	1,300	
Employee training	300	300
Totals	24,700–36,700	10,600

TABLE 31.—COST FOR ILLUSTRATIVE SMALL YEAR ROUND CONCENTRATED ORANGE JUICE PROCESSOR

Type of cost	Cost in first year	Cost in subsequent years
Monitoring and documenting of SOP 's	$340	$340
Hazard analysis	250	
Validation	1,000	
Training of coordinator	1,300	
Totals	2,900	300

TABLE 32.—COST FOR ILLUSTRATIVE SMALL YEAR ROUND UNPASTEURIZED ORANGE JUICE PROCESSOR

Type of cost	Cost in first year	Cost in subsequent years
Develop SOP's	$260	
Monitoring and documenting of SOP 's	340	$340
Hazard analysis	250	
HACCP plan	750	
Pathogen controls	18,000–30,000	7,900
Corrective action Plan	50	
Corrective actions	1,460	340
Verification	1,350	1,350
Validation	2,000	1,000
Process verification testing	7,800	7,800
Annualized cost of Process Verification Failure	2,600	2,600
HACCP monitoring and Recordkeeping	5,600	5,600
Record maintenance & storage	830	830
Training of coordinator	1,300	
Employee training	500	500
Totals	43,100–55,100	28,300

TABLE 33.—COSTS FOR ILLUSTRATIVE LARGE YEAR ROUND APPLE JUICE PROCESSOR

Type of cost	Cost in first year	Cost in subsequent years
Develop SOP's	$260	

TABLE 33.—COSTS FOR ILLUSTRATIVE LARGE YEAR ROUND APPLE JUICE PROCESSOR—Continued

Type of cost	Cost in first year	Cost in subsequent years
Sanitation SOP's	500	
Monitoring and documenting of SOP 's	340	$340
Hazard analysis	250	
HACCP plan	750	
Natural toxin control	4,500	4,500
Corrective action plan	50	
Corrective actions	1,460	340
Verification	1,350	1,350
Validation	1,200	1,200
HACCP monitoring and recordkeeping	5,600	5,600
Record maintenance	680	680
Record storage	150	
Training of coordinator	1,300	
Employee training	8,300	8,300
Totals	24,000	20,000

TABLE 34.—COSTS FOR ILLUSTRATIVE LARGE YEAR ROUND SHELF-STABLE TOMATO JUICE PROCESSOR

Type of cost	Cost in first year	Cost in subsequent years
Hazard analysis	$250	
Validation	600	
Training of coordinator	1,300	
Totals	2,000	$0

Some comments stated that the rule would be burdensome on small juice processors and that some processors would have to cease producing juice. FDA is issuing a tiered, extended compliance period giving the smallest firms the most time to comply with the rule. Extending the compliance period by 1 year for small firms could save each one $500 to $31,600 (using a 7 percent discount rate). Extending the compliance period by 2 years for very small firms could save each one $900 to $61,000 (using a 7 percent discount rate). These savings accrue just from delaying the time at which the expenditures for compliance must take place. The amount of savings increases as the cost of compliance increases. One effect of the cost savings will be to reduce small firm failure. FDA believes that this extended compliance period will provide small firms with significant relief in the cost of preparing for HACCP and making necessary changes to comply with this rule.

2. Professional Skills Required for Compliance

The RFA requires a description of the professional skills required for compliance with this rule. Table 35 describes the professional skills required for compliance with the various activities required by this rule.

TABLE 35.—PROFESSIONAL SKILLS REQUIRED FOR COMPLIANCE

Required activity	Section of rule	Professional skills required for compliance
Developing prerequisite program SOP 's	§ 120.6	Managers familiar with incoming materials and plant sanitation.
Implementing sanitation controls with corrections of deviations from prerequisite program SOP's.	§ 120.6	Production workers who are able to maintain the sanitation controls as described in the sanitation SOP's and supervisors or managers who can determine what corrective actions are necessary for deviations from SOP 's.
Monitoring and documenting of prerequisite Program SOP's.	§ 120.6	Production workers who are appropriately trained to monitor and keep records on observations and measurements for prerequisite program SOP 's.
Developing hazard analysis and HACCP plan..	§§ 120.7 and 120.8	Supervisors or managers who fulfill the role of HACCP coordinator as well as microbiologists, chemists, and attorneys.
Implementing pathogen controls	§ 120.8	Production workers who are appropriately trained to monitor and keep records on observations and measurements at CCP 's.
Implementing pesticide controls	§ 120.8	Production workers who are appropriately trained to carry out tests, to monitor, and to keep records on observations and measurements at CCP 's.
Tracking corrective actions	§ 120.10	Production workers who are trained to take corrective action described in corrective action plans and supervisors or managers who can determine what corrective actions are necessary for deviations from CL 's.
Verification	§ 120.11	Supervisors or managers who fulfill the role of HACCP coordinator.
Validation	§ 120.11	Food scientists or food technologists who can perform a scientific review of the process.
Process verification	§ 120.25	Microbiologists and production workers who are trained to take process verification samples and food scientists or food technologists who can perform a scientific review of the process in the event of a process verification failure.

TABLE 35.—PROFESSIONAL SKILLS REQUIRED FOR COMPLIANCE—Continued

Required activity	Section of rule	Professional skills required for compliance
Monitoring and recordkeeping	§ 120.12	Production workers who are appropriately trained to monitor and keep records on observations and measurements at CCP 's.
Record maintenance	§ 120.12	Clerical or production workers.
HACCP coordinator training coordinator	§ 120.13	Supervisors or managers who fulfill the role of HACCP.
HACCP employee training	§ 120.13	Clerical and production workers.
Imports	§ 120.14	Clerical workers as well as supervisors or managers who fulfill the role of HACCP coordinator.

3. Recordkeeping requirements

The RFA requires a description of the recordkeeping requirements of the proposed rule. Table 36 shows the provisions for which records need to be made and kept by small businesses, the number of small businesses affected, the annual frequency that the records need to be made, the amount of time needed for making each record, and the total number of hours for each provision in the first year and then in subsequent years.

TABLE 36.—SMALL BUSINESS RECORDKEEPING REQUIREMENTS

21 CFR provisions	Number of small entities keeping records	Annual frequency	Hours per record per small entity	Total hours first year	Total subsequent years
120.6 Monitoring and Recordkeeping of SOP 's	1,660	16	0.5	13,300	13,300
	210	52	....	5,500	5,500
120.7 Hazard analysis	2,125	1	20	42,500	0
120.8 HACCP plan	1,930	1	60	115,800	0
120.8 Pesticide Controls by Supplier Certificate	1,700	160	.02	5,400	5,400
120.11 Verification	1,450	16	2	46,400	46,400
	380	52	[1] 8	39,500	39,500
120.11 Validation	1,450	1	[2] 4	11,600	5,800
	380	2	....	6,100	3,000
120.12 HACCP records	1,450	1,440	.05	104,400	104,400
	380	8,640	....	164,200	164,200
120.12 Record maintenance	1,450	16	1	23,200	23,200
Totals	....	....	....	598,000	431,000

[1] First year. [2] Subsequent year.

D. Minimizing the Burden on Small Entities

The RFA requires an evaluation of any regulatory overlaps and regulatory alternatives that would minimize the costs to small entities.

There are two alternatives that the agency has considered to provide regulatory relief for small entities. First, FDA considered and is proposing the option of exempting some small entities from the requirements of these rules. Second, FDA considered and is proposing the option of lengthening the compliance period for small entities.

1. Exempt Small Entities

One alternative for alleviating the burden for small entities would be to exempt them from the provisions of this rule. FDA proposed to exempt retailers who, for the purposes of this rule, the agency tentatively decided would include very small businesses that make juice on their premises and whose total sales of juice and juice products do not exceed 40,000 gallons per year and who sell directly to consumers or directly to consumers and other retailers.

Revenue from sales of 40,000 gallons of nonheat treated juice may be approximately $160,000 with annual profits ranging from $1,600 to $16,000 per year (1 percent to 10 percent). This exemption covered most of the very small businesses, although less than 15 percent of the volume of unpasteurized juice. However, packaged products sold by these types of processors are covered under the labeling rule.

As detailed in response to comment 47, the comments that FDA received on this exemption were almost entirely critical of the exemption. Based upon the comments and other information available to the agency, FDA has decided not to finalize this proposed exemption.

2. Extend Compliance Period

FDA is issuing a tiered, extended compliance period giving the smallest firms the most time to comply with the rule. Extending the compliance period by 1 year for small firms could save each one $500 to $31,600 (using a 7 percent discount rate). Extending the compliance period by 2 years for very small firms could save each one $900 to $61,000 (using a 7 percent discount rate). These savings accrue just from delaying the time at which the expenditures for compliance must take place. The amount of savings increases as the cost of compliance increases.

Additional savings may come as smaller firms learn more efficient compliance strategies from larger firms that must comply earlier and as new, less costly technologies that may be employed by small firms are developed during the extended compliance period. FDA is unable to quantify these additional savings of the extended compliance period although one effect of the cost savings will be to reduce small firm failure.

FDA believes that this extended compliance period will provide small firms with significant relief in the cost of preparing for HACCP and making

necessary changes to comply with this rule.

E. Summary

FDA has examined the impact of this rule on small businesses in accordance with the RFA. This analysis, together with the rest of the preamble constitutes the final RFA. FDA has determined that this rule is likely to have a significant impact on a substantial number of small entities.

VII. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). A description of these information provisions is given below with an estimate of the annual recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Hazard Analysis and Critical Control Point (HACCP) Procedures for the Safe and Sanitary Processing of Juice—Recordkeeping requirements for processors of fruit and vegetable juices

Description: This final rule mandates the application of HACCP procedures to fruit and vegetable juice processing. HACCP is a preventative system of hazard control that can be used by all food processors to ensure the safety of their products to consumers. FDA is finalizing these regulations because a system of preventative control is the most effective and efficient way to ensure that these food products are safe. FDA's mandate to ensure the safety of the nation's food supply is derived principally from the act (21 U.S.C. 321 *et seq.*). Under the act, FDA has authority to ensure that all foods in interstate commerce, or that have been shipped in interstate commerce, are not contaminated or otherwise adulterated, are produced and held under sanitary conditions, and are not misbranded or deceptively packaged; under 21 U.S.C. 371, the act authorizes the agency to issue regulations for its efficient enforcement. The agency also has authority under the Public Health Service Act (42 U.S.C. 264) to issue and enforce regulations to prevent the introduction, transmission, or spread of communicable diseases from one State to another other State. Information development and recordkeeping are essential parts of any HACCP system. The information collection requirements of this rule are narrowly tailored to focus on the development of appropriate controls and documenting those aspects of processing that are critical to food safety. Through this final rule, FDA is implementing its authority under section 402(a)(4) of the act. The information development and recordkeeping requirements of this final rule are likewise an implementation of section 402(a)(4) of the act.

Description of Respondents: Businesses and other for-profit institutions.

In the **Federal Register** of April 24, 1998, the agency requested comments on the proposed collection of information provisions contained in the HACCP proposal. One comment was received. This comment asserted that the change in sequence in the proposed rule for the last two steps of the seven principles of HACCP is a change that will result in many paperwork changes. The seven principles of HACCP have been articulated by the NACMCF.

The agency does not agree with this comment. Prior to 1997, the NACMCF listed establishing recordkeeping and documentation procedures and establishing verification procedures as the sixth and seventh principles of HACCP; this is the order in which the principles are reflected in FDA's seafood HACCP regulation, part 123. When the NACMCF revised its HACCP principles and application guidelines in 1997, it reversed the order of the last two steps. Thus, the sequence in part 120 for the seven principles of HACCP is identical to the sequence most recently outlined by NACMCF. The 1997 change does not require a change in the analytical approach or in the information to be assembled by juice processors as they apply the HACCP principles to their process. The agency does not anticipate that there will be a need for processors to complete additional paperwork simply because there has been a change in the order of the seven principles of HACCP or because there will be a slight difference in the juice HACCP regulation and the seafood HACCP regulation. It is FDA's position that as long as all the essential elements are present in the written HACCP plan, the plan will be complete.

FDA estimates the burden of this collection of information as follows:

TABLE 37.—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR sections	Number of recordkeepers	Annual frequency of records	Total annual records	Hours per record	Total hours
120.6(a) & 120.12(a)(1) & (b)	1,875	1	1,875	4	[2] 7,500
120.6(c) & 120.12(a)(1) & (b)	1,875	365	684,375	0.1	68,437.5
120.7; 120.10 (a); & 120.12(a)(2), (b) & (c)	2,300	1.1	2,530	20	50,600
120.8 (except monitoring records required under 120.8(b)(7)); & 120.12(a)(3),(b)& (c)	1,840	1	1,840	60	[2] 110,400
120.8(b)(7) & 120.12(a)(4)(i), & (b)	1,450	14,600	21,170,000	0.01	211,700
120.10(c) & 120.12(a)(4)(ii), & (b)	1,840	12	22,080	0.1	2,208
120.11(a)(1)(iv); 120.11(a)(2); 120.12(a)(5)	1,840	52	95,680	0.1	9,568
120.11(b) & 120.12(a)(5), & (b)	1,840	1	1,840	4	7,360
120.11 (c) & 120.12(a)(5) & (b)	1,840	1	1,840	4	7,360
120.14(a)(2); & 120.14 (c) & (d)	308	1	308	4	1,232
Totals	First year—476,365.5		Subsequent years —358,465.5		

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] First year only.

The burden estimates in table 37 above are based on an estimate of the total number of juice manufacturing plants (*i.e.*, 2,300) affected by this final rule. Included in this total are 850 plants currently identified in FDA's OEI plus 1,220 very small apple juice manufacturers and 230 very small orange juice manufacturers (see table 13

in section V). The figures in table 36 are derived by estimating the number of plants affected by each portion of this final rule and multiplying the corresponding number by the number of records required annually and the hours needed to complete the record. These numbers were obtained from the agency's final RIA prepared for this final rule.

Moreover, these estimates assume that every processor will prepare SSOP's and a HACCP plan and maintain the associated monitoring records and that every importer will require product safety specifications. In fact, there are likely to be some small number of juice processors that, based upon their hazard analysis, determine that they are not required to have a HACCP plan under this final rule.

Table 37 provides a breakdown of the total estimated recordkeeping burden for the first year and subsequent years. The estimates in this table have been reviewed by the agency's HACCP experts, who have practical experience in observing various processing operations and related recordkeeping activities.

The information collection provisions of this final rule have been submitted to OMB for review.

Prior to the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

VIII. Environmental Impact

The agency has previously considered the environmental effects of the action being taken in this final rule. As announced in the proposed rule published in the **Federal Register** of April 24, 1998 (63 FR 20450) (Ref. 2), the agency determined that under 21 CFR 25.30(j) this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement was required.

(Comment 158) Two comments were received in response to the potential environmental impact of this rule. One comment stated that "* * * the extensive recordkeeping requirements under the juice proposal will increase paper consumption significantly, which will not be considered 'environmentally friendly.'" This comment did not provide evidence to support this assertion.

FDA agrees that the recordkeeping requirement in the HACCP final rule may increase paper consumption. However, the agency disagrees that this increase will be significant. The agency believes that the paper used for the required recordkeeping will be a very small fraction of the overall amount of paper used in the United States. Therefore, this use will not significantly increase the production, use and disposal of paper and, thus, will not result in significant adverse impacts on the environment. Additionally, FDA notes that § 120.12(g) of the final rule permits records to be maintained electronically. When the regulated entities maintain records electronically, the need for paper is reduced.

(Comment 159) One comment on the proposed rule stated that efforts to achieve 5-log reduction will lead to possible excessive pollution of the environment from disposal of unessential sanitizers. This comment did not provide evidence to support this assertion.

The agency has concluded that even if some increase in the use of sanitizing products should result, the products used would be either registered with the U.S. EPA or regulated by FDA for use on food contact articles under § 178.1010 (21 CFR 178.1010) or both. Environmental review is part of EPA's pesticide registration process and is part of FDA's process for listing sanitizing solutions under § 178.1010. FDA expects processors to use all sanitizing products according to directions on product labels and under the supervision of experienced persons. Use of the sanitizing products in this manner should ensure that any increased use will not result in adverse effects on the environment.

The agency has concluded that these comments on the potential for adverse environmental effects will not affect its previous determination that this action will not have a significant impact on the human environment and that an environmental impact statement is not required.

IX. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government (Ref. 75). Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

X. References

The following information has been placed on display in the Dockets Management Branch (address above), and may be seen by interested persons between 9 a.m. and 4 p.m. Monday through Friday.

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List of Subjects in 21 CFR Part 120

Foods, Fruit juices, Imports, Reporting and recordkeeping requirements, Vegetable juices.

Therefore, under the Federal Food, Drug, and Cosmetic Act, under the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR chapter I is amended as follows:

1. Part 120 is added to read as follows:

PART 120—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

Subpart A—General Provisions

Subpart B—Pathogen Reduction

Authority: 21 U.S.C. 321, 342, 343, 346, 348, 371, 374, 379e, 381, 393; 42 U.S.C. 241, 242l, 264.

Subpart A—General Provisions

§ 120.1 Applicability.

(a) Any juice sold as such or used as an ingredient in beverages shall be processed in accordance with the requirements of this part. Juice means the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or puree. The requirements of this part shall apply to any juice regardless of whether the juice, or any of its ingredients, is or has been shipped in interstate commerce (as defined in section 201(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321(b)). Raw agricultural ingredients of juice are not subject to the requirements of this part. Processors should apply existing agency guidance to minimize microbial food safety hazards for fresh fruits and vegetables in handling raw agricultural products.

(b) The regulations in this part shall be effective January 22, 2002. However, by its terms, this part is not binding on small and very small businesses until the dates listed in paragraphs (b)(1) and (b)(2) of this section.

(1) For small businesses employing fewer than 500 persons the regulations in this part are binding on January 21, 2003.

(2) For very small businesses that have either total annual sales of less than $500,000, or if their total annual sales are greater than $500,000 but their total food sales are less than $50,000; or the person claiming this exemption employed fewer than an average of 100 full-time equivalent employees and fewer than 100,000 units of juice were sold in the United States, the regulations are binding on January 20, 2004.

§ 120.3 Definitions.

The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act, § 101.9(j)(18)(vi), and part 110 of this chapter are applicable to

such terms when used in this part, except where redefined in this part. The following definitions shall also apply:

(a) *Cleaned* means washed with water of adequate sanitary quality.

(b) *Control* means to prevent, eliminate, or reduce.

(c) *Control measure* means any action or activity to prevent, reduce to acceptable levels, or eliminate a hazard.

(d) *Critical control point* means a point, step, or procedure in a food process at which a control measure can be applied and at which control is essential to reduce an identified food hazard to an acceptable level.

(e) *Critical limit* means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food hazard.

(f) *Culled* means separation of damaged fruit from undamaged fruit. For processors of citrus juices using treatments to fruit surfaces to comply with § 120.24, *culled* means undamaged, tree-picked fruit that is U.S. Department of Agriculture choice or higher quality.

(g) *Food hazard* means any biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

(h) *Importer* means either the U.S. owner or consignee at the time of entry of a food product into the United States, or the U.S. agent or representative of the foreign owner or consignee at the time of entry into the United States. The importer is responsible for ensuring that goods being offered for entry into the United States are in compliance with all applicable laws. For the purposes of this definition, the importer is ordinarily not the custom house broker, the freight forwarder, the carrier, or the steamship representative.

(i) *Monitor* means to conduct a planned sequence of observations or measurements to assess whether a process, point, or procedure is under control and to produce an accurate record for use in verification.

(j)(1) *Processing* means activities that are directly related to the production of juice products.

(2) For purposes of this part, processing does not include:

(i) Harvesting, picking, or transporting raw agricultural ingredients of juice products, without otherwise engaging in processing; and

(ii) The operation of a retail establishment.

(k) Processor means any person engaged in commercial, custom, or institutional processing of juice products, either in the United States or in a foreign country, including any person engaged in the processing of juice products that are intended for use in market or consumer tests.

(l) *Retail establishment* is an operation that provides juice directly to the consumers and does not include an establishment that sells or distributes juice to other business entities as well as directly to consumers. "Provides" includes storing, preparing, packaging, serving, and vending.

(m) *Shall* is used to state mandatory requirements.

(n) *Shelf-stable product* means a product that is hermetically sealed and, when stored at room temperature, should not demonstrate any microbial growth.

(o) *Should* is used to state recommended or advisory procedures or to identify recommended equipment.

(p) *Validation* means that element of verification focused on collecting and evaluating scientific and technical information to determine whether the HACCP plan, when properly implemented, will effectively control the identified food hazards.

(q) *Verification* means those activities, other than monitoring, that establish the validity of the HACCP plan and that the system is operating according to the plan.

§ 120.5 Current good manufacturing practice.

Part 110 of this chapter applies in determining whether the facilities, methods, practices, and controls used to process juice are safe, and whether the food has been processed under sanitary conditions.

§ 120.6 Sanitation standard operating procedures.

(a) *Sanitation controls.* Each processor shall have and implement a sanitation standard operating procedure (SSOP) that addresses sanitation conditions and practices before, during, and after processing. The SSOP shall address:

(1) Safety of the water that comes into contact with food or food contact surfaces or that is used in the manufacture of ice;

(2) Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments;

(3) Prevention of cross contamination from insanitary objects to food, food packaging material, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to processed product;

(4) Maintenance of hand washing, hand sanitizing, and toilet facilities;

(5) Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants;

(6) Proper labeling, storage, and use of toxic compounds;

(7) Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces; and

(8) Exclusion of pests from the food plant.

(b) *Monitoring.* The processor shall monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices specified in part 110 of this chapter that are appropriate both to the plant and to the food being processed. Each processor shall correct, in a timely manner, those conditions and practices that are not met.

(c) *Records.* Each processor shall maintain SSOP records that, at a minimum, document the monitoring and corrections prescribed by paragraph (b) of this section. These records are subject to the recordkeeping requirements of § 120.12.

(d) *Relationship to Hazard Analysis and Critical Control Point (HACCP) plan.* Sanitation standard operating procedure controls may be included in the HACCP plan required under § 120.8(b). However, to the extent that they are implemented in accordance with this section, they need not be included in the HACCP plan.

§ 120.7 Hazard analysis.

(a) Each processor shall develop, or have developed for it, a written hazard analysis to determine whether there are food hazards that are reasonably likely to occur for each type of juice processed by that processor and to identify control measures that the processor can apply to control those hazards. The written hazard analysis shall consist of at least the following:

(1) Identification of food hazards;

(2) An evaluation of each food hazard identified to determine if the hazard is reasonably likely to occur and thus, constitutes a food hazard that must be addressed in the HACCP plan. A food hazard that is reasonably likely to occur is one for which a prudent processor would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that, in the absence of those controls, the food hazard will occur in the particular type of product being processed. This

evaluation shall include an assessment of the severity of the illness or injury if the food hazard occurs;

(3) Identification of the control measures that the processor can apply to control the food hazards identified as reasonably likely to occur in paragraph (a)(2) of this section;

(4) Review of the current process to determine whether modifications are necessary; and

(5) Identification of critical control points.

(b) The hazard analysis shall include food hazards that can be introduced both within and outside the processing plant environment, including food hazards that can occur before, during, and after harvest. The hazard analysis shall be developed by an individual or individuals who have been trained in accordance with § 120.13 and shall be subject to the recordkeeping requirements of § 120.12.

(c) In evaluating what food hazards are reasonably likely to occur, consideration should be given, at a minimum, to the following:

(1) Microbiological contamination;

(2) Parasites;

(3) Chemical contamination;

(4) Unlawful pesticides residues;

(5) Decomposition in food where a food hazard has been associated with decomposition;

(6) Natural toxins;

(7) Unapproved use of food or color additives;

(8) Presence of undeclared ingredients that may be allergens; and

(9) Physical hazards.

(d) Processors should evaluate product ingredients, processing procedures, packaging, storage, and intended use; facility and equipment function and design; and plant sanitation, including employee hygiene, to determine the potential effect of each on the safety of the finished food for the intended consumer.

(e) HACCP plans for juice need not address the food hazards associated with microorganisms and microbial toxins that are controlled by the requirements of part 113 or part 114 of this chapter. A HACCP plan for such juice shall address any other food hazards that are reasonably likely to occur.

§ 120.8 Hazard Analysis and Critical Control Point (HACCP) plan.

(a) *HACCP plan.* Each processor shall have and implement a written HACCP plan whenever a hazard analysis reveals one or more food hazards that are reasonably likely to occur during processing, as described in § 120.7. The HACCP plan shall be developed by an individual or individuals who have been trained in accordance with § 120.13 and shall be subject to the recordkeeping requirements of § 120.12. A HACCP plan shall be specific to:

(1) Each location where juice is processed by that processor; and

(2) Each type of juice processed by the processor. The plan may group types of juice products together, or group types of production methods together, if the food hazards, critical control points, critical limits, and procedures required to be identified and performed by paragraph (b) of this section are essentially identical, provided that any required features of the plan that are unique to a specific product or method are clearly delineated in the plan and are observed in practice.

(b) *The contents of the HACCP plan.* The HACCP plan shall, at a minimum:

(1) List all food hazards that are reasonably likely to occur as identified in accordance with § 120.7, and that thus must be controlled for each type of product;

(2) List the critical control points for each of the identified food hazards that is reasonably likely to occur, including as appropriate:

(i) Critical control points designed to control food hazards that are reasonably likely to occur and could be introduced inside the processing plant environment; and

(ii) Critical control points designed to control food hazards introduced outside the processing plant environment, including food hazards that occur before, during, and after harvest;

(3) List the critical limits that shall be met at each of the critical control points;

(4) List the procedures, and the frequency with which they are to be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;

(5) Include any corrective action plans that have been developed in accordance with § 120.10(a), and that are to be followed in response to deviations from critical limits at critical control points;

(6) List the validation and verification procedures, and the frequency with which they are to be performed, that the processor will use in accordance with § 120.11; and

(7) Provide for a recordkeeping system that documents the monitoring of the critical control points in accordance with § 120.12. The records shall contain the actual values and observations obtained during monitoring.

(c) *Sanitation.* Sanitation controls may be included in the HACCP plan. However, to the extent that they are monitored in accordance with § 120.6, they are not required to be included in the HACCP plan.

§ 120.9 Legal basis.

Failure of a processor to have and to implement a Hazard Analysis and Critical Control Point (HACCP) system that complies with §§ 120.6, 120.7, and 120.8, or otherwise to operate in accordance with the requirements of this part, shall render the juice products of that processor adulterated under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. Whether a processor's actions are consistent with ensuring the safety of juice will be determined through an evaluation of the processor's overall implementation of its HACCP system.

§ 120.10 Corrective actions.

Whenever a deviation from a critical limit occurs, a processor shall take corrective action by following the procedures set forth in paragraph (a) or paragraph (b) of this section.

(a) Processors may develop written corrective action plans, which become part of their HACCP plans in accordance with § 120.8(b)(5), by which processors predetermine the corrective actions that they will take whenever there is a deviation from a critical limit. A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that:

(1) No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation; and

(2) The cause of the deviation is corrected.

(b) When a deviation from a critical limit occurs, and the processor does not have a corrective action plan that is appropriate for that deviation, the processor shall:

(1) Segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met;

(2) Perform or obtain a review to determine the acceptability of the affected product for distribution. The review shall be performed by an individual or individuals who have adequate training or experience to perform such review;

(3) Take corrective action, when necessary, with respect to the affected product to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation;

(4) Take corrective action, when necessary, to correct the cause of the deviation; and

(5) Perform or obtain timely verification in accordance with § 120.11, by an individual or individuals who have been trained in accordance with § 120.13, to determine whether modification of the HACCP plan is required to reduce the risk of recurrence of the deviation, and to modify the HACCP plan as necessary.

(c) All corrective actions taken in accordance with this section shall be fully documented in records that are subject to verification in accordance with § 120.11(a)(1)(iv)(B) and the recordkeeping requirements of § 120.12.

§ 120.11 Verification and validation.

(a) *Verification.* Each processor shall verify that the Hazard Analysis and Critical Control Point (HACCP) system is being implemented according to design.

(1) Verification activities shall include:

(i) A review of any consumer complaints that have been received by the processor to determine whether such complaints relate to the performance of the HACCP plan or reveal previously unidentified critical control points;

(ii) The calibration of process monitoring instruments;

(iii) At the option of the processor, the performance of periodic end-product or in-process testing; except that processors of citrus juice that rely in whole or in part on surface treatment of fruit shall perform end-product testing in accordance with § 120.25.

(iv) A review, including signing and dating, by an individual who has been trained in accordance with § 120.13, of the records that document:

(A) The monitoring of critical control points. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that the records document values that are within the critical limits. This review shall occur within 1 week (7 days) of the day that the records are made;

(B) The taking of corrective actions. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that appropriate corrective actions were taken in accordance with § 120.10. This review shall occur within 1 week (7 days) of the day that the records are made; and

(C) The calibrating of any process monitoring instruments used at critical control points and the performance of any periodic end-product or in-process testing that is part of the processor's verification activities. The purpose of these reviews shall be, at a minimum, to ensure that the records are complete and that these activities occurred in accordance with the processor's written procedures. These reviews shall occur within a reasonable time after the records are made; and

(v) The following of procedures in § 120.10 whenever any verification procedure, including the review of consumer complaints, establishes the need to take a corrective action; and

(vi) Additional process verification if required by § 120.25.

(2) Records that document the calibration of process monitoring instruments, in accordance with paragraph (a)(1)(iv)(B) of this section, and the performance of any periodic end-product and in-process testing, in accordance with paragraph (a)(1)(iv)(C) of this section, are subject to the recordkeeping requirements of § 120.12.

(b) *Validation of the HACCP plan.* Each processor shall validate that the HACCP plan is adequate to control food hazards that are reasonably likely to occur; this validation shall occur at least once within 12 months after implementation and at least annually thereafter or whenever any changes in the process occur that could affect the hazard analysis or alter the HACCP plan in any way. Such changes may include changes in the following: Raw materials or source of raw materials; product formulation; processing methods or systems, including computers and their software; packaging; finished product distribution systems; or the intended use or consumers of the finished product. The validation shall be performed by an individual or individuals who have been trained in accordance with § 120.13 and shall be subject to the recordkeeping requirements of § 120.12. The HACCP plan shall be modified immediately whenever a validation reveals that the plan is no longer adequate to fully meet the requirements of this part.

(c) *Validation of the hazard analysis.* Whenever a juice processor has no HACCP plan because a hazard analysis has revealed no food hazards that are reasonably likely to occur, the processor shall reassess the adequacy of that hazard analysis whenever there are any changes in the process that could reasonably affect whether a food hazard exists. Such changes may include changes in the following: Raw materials or source of raw materials; product formulation; processing methods or systems, including computers and their software; packaging; finished product distribution systems; or the intended use or intended consumers of the finished product. The validation of the hazard analysis shall be performed by an individual or individuals who have been trained in accordance with § 120.13, and, records documenting the validation shall be subject to the recordkeeping requirements of § 120.12.

§ 120.12 Records.

(a) *Required records.* Each processor shall maintain the following records documenting the processor's Hazard Analysis and Critical Control Point (HACCP) system:

(1) Records documenting the implementation of the sanitation standard operating procedures (SSOP's) (see § 120.6);

(2) The written hazard analysis required by § 120.7;

(3) The written HACCP plan required by § 120.8;

(4) Records documenting the ongoing application of the HACCP plan that include:

(i) Monitoring of critical control points and their critical limits, including the recording of actual times, temperatures, or other measurements, as prescribed in the HACCP plan; and

(ii) Corrective actions, including all actions taken in response to a deviation; and

(5) Records documenting verification of the HACCP system and validation of the HACCP plan or hazard analysis, as appropriate.

(b) *General requirements.* All records required by this part shall include:

(1) The name of the processor or importer and the location of the processor or importer, if the processor or importer has more than one location;

(2) The date and time of the activity that the record reflects, except that records required by paragraphs (a)(2), (a)(3), and (a)(5) of this section need not include the time;

(3) The signature or initials of the person performing the operation or creating the record; and

(4) Where appropriate, the identity of the product and the production code, if any. Processing and other information shall be entered on records at the time that it is observed. The records shall contain the actual values and observations obtained during monitoring.

(c) *Documentation.* (1) The records in paragraphs (a)(2) and (a)(3) of this section shall be signed and dated by the most responsible individual onsite at the processing facility or by a higher level official of the processor. These signatures shall signify that these records have been accepted by the firm.

(2) The records in paragraphs (a)(2) and (a)(3) of this section shall be signed and dated:

(i) Upon initial acceptance;

(ii) Upon any modification; and

(iii) Upon verification and validation in accordance with § 120.11

(d) *Record retention.* (1) All records required by this part shall be retained at the processing facility or at the importer's place of business in the United States for, in the case of perishable or refrigerated juices, at least 1 year after the date that such products were prepared, and for, in the case of frozen, preserved, or shelf stable products, 2 years or the shelf life of the product, whichever is greater, after the date that the products were prepared.

(2) Offsite storage of processing records required by paragraphs (a)(1) and (a)(4) of this section is permitted after 6 months following the date that the monitoring occurred, if such records can be retrieved and provided onsite within 24 hours of request for official review. Electronic records are considered to be onsite if they are accessible from an onsite location and comply with paragraph (g) of this section.

(3) If the processing facility is closed for a prolonged period between seasonal packs, the records may be transferred to some other reasonably accessible location at the end of the seasonal pack but shall be immediately returned to the processing facility for official review upon request.

(e) *Official review.* All records required by this part shall be available for review and copying at reasonable times.

(f) *Public disclosure.* (1) All records required by this part are not available for public disclosure unless they have been previously disclosed to the public, as defined in § 20.81 of this chapter, or unless they relate to a product or ingredient that has been abandoned and no longer represent a trade secret or confidential commercial or financial information as defined in § 20.61 of this chapter.

(2) Records required to be maintained by this part are subject to disclosure to the extent that they are otherwise publicly available, or that disclosure could not reasonably be expected to cause a competitive hardship, such as generic type HACCP plans that reflect standard industry practices.

(g) *Records maintained on computers.* The maintenance of computerized records, in accordance with part 11 of this chapter, is acceptable. § 120.13 *Training.*

(a) Only an individual who has met the requirements of paragraph (b) of this section shall be responsible for the following functions:

(1) Developing the hazard analysis, including delineating control measures, as required by § 120.7.

(2) Developing a Hazard Analysis and Critical Control Point (HACCP) plan that is appropriate for a specific processor, in order to meet the requirements of § 120.8;

(3) Verifying and modifying the HACCP plan in accordance with the corrective action procedures specified in § 120.10(b)(5) and the validation activities specified in § 120.11(b) and (c); and § 120.7;

(4) Performing the record review required by § 120.11(a)(1)(iv).

(b) The individual performing the functions listed in paragraph (a) of this section shall have successfully completed training in the application of HACCP principles to juice processing at least equivalent to that received under standardized curriculum recognized as adequate by the Food and Drug Administration, or shall be otherwise qualified through job experience to perform these functions. Job experience may qualify an individual to perform these functions if such experience has provided knowledge at least equivalent to that provided through the standardized curriculum. The trained individual need not be an employee of the processor.

§ 120.14 Application of requirements to imported products.

This section sets forth specific requirements for imported juice.

(a) *Importer requirements.* Every importer of juice shall either:

(1) Obtain the juice from a country that has an active memorandum of understanding (MOU) or similar agreement with the Food and Drug Administration, that covers the food and documents the equivalency or compliance of the inspection system of the foreign country with the U.S. system, accurately reflects the relationship between the signing parties, and is functioning and enforceable in its entirety; or

(2) Have and implement written procedures for ensuring that the juice that such importer receives for import into the United States was processed in accordance with the requirements of this part. The procedures shall provide, at a minimum:

(i) Product specifications that are designed to ensure that the juice is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act because it may be injurious to health or because it may have been processed under insanitary conditions; and

(ii) Affirmative steps to ensure that the products being offered for entry were processed under controls that meet the requirements of this part. These steps may include any of the following:

(A) Obtaining from the foreign processor the Hazard Analysis and Critical Control Point (HACCP) plan and prerequisite program of the standard operating procedure records required by this part that relate to the specific lot of food being offered for import;

(B) Obtaining either a continuing or lot specific certificate from an appropriate foreign government inspection authority or competent third party certifying that the imported food has been processed in accordance with the requirements of this part;

(C) Regularly inspecting the foreign processor's facilities to ensure that the imported food is being processed in accordance with the requirements of this part;

(D) Maintaining on file a copy, in English, of the foreign processor's hazard analysis and HACCP plan, and a written guarantee from the foreign processor that the imported food is processed in accordance with the requirements of this part;

(E) Periodically testing the imported food, and maintaining on file a copy, in English, of a written guarantee from the foreign processor that the imported food is processed in accordance with the requirements of this part; or

(F) Other such verification measures as appropriate that provide an equivalent level of assurance of compliance with the requirements of this part.

(b) *Competent third party.* An importer may hire a competent third party to assist with or perform any or all of the verification activities specified in paragraph (a)(2) of this section, including writing the importer's verification procedures on the importer's behalf.

(c) *Records.* The importer shall maintain records, in English, that document the performance and results of the affirmative steps specified in paragraph (a)(2)(ii) of this section. These records shall be subject to the applicable provisions of § 120.12.

(d) *Determination of compliance.* The importer shall provide evidence that all juice offered for entry into the United States has been processed under conditions that comply with this part. If assurances do not exist that an imported juice has been processed under conditions that are equivalent to those required of domestic processors under this part, the product will appear to be adulterated and will be denied entry.

Subpart B—Pathogen Reduction

§ 120.20 General.

This subpart augments subpart A of this part by setting forth specific requirements for process controls.

§ 120.24 Process controls.

(a) In order to meet the requirements of subpart A of this part, processors of juice products shall include in their Hazard Analysis and Critical Control Point (HACCP) plans control measures that will consistently produce, at a minimum, a 5 log (*i.e.*, 10^5) reduction, for a period at least as long as the shelf life of the product when stored under normal and moderate abuse conditions, in the pertinent microorganism. For the purposes of this regulation, the "pertinent microorganism" is the most resistant microorganism of public health significance that is likely to occur in the juice. The following juice processors are exempt from this paragraph:

(1) A juice processor that is subject to the requirements of part 113 or part 114 of this chapter; and

(2) A juice processor using a single thermal processing step sufficient to achieve shelf-stability of the juice or a thermal concentration process that includes thermal treatment of all ingredients, provided that the processor includes a copy of the thermal process used to achieve shelf-stability or concentration in its written hazard analysis required by § 120.7.

(b) All juice processors shall meet the requirements of paragraph (a) of this section through treatments that are applied directly to the juice, except that citrus juice processors may use treatments to fruit surfaces, provided that the 5-log reduction process begins after culling and cleaning as defined in § 120.3(a) and (f) and the reduction is accomplished within a single production facility.

(c) All juice processors shall meet the requirements of paragraphs (a) and (b) of this section and perform final product packaging within a single production facility operating under current good manufacturing practices. Processors claiming an exemption under paragraph (a)(1) or (a)(2) of this section shall also process and perform final product packaging of all juice subject to the claimed exemption within a single production facility operating under current good manufacturing practices.

§ 120.25 Process verification for certain processors.

Each juice processor that relies on treatments that do not come into direct contact with all parts of the juice to achieve the requirements of § 120.24 shall analyze the finished product for biotype I *Escherichia coli* as follows:

(a) One 20 milliliter (mL) sample (consisting of two 10 mL subsamples) for each 1,000 gallons of juice produced shall be sampled each production day. If less than 1,000 gallons of juice is produced per day, the sample must be taken for each 1,000 gallons produced but not less than once every 5 working days that the facility is producing that juice. Each subsample shall be taken by randomly selecting a package of juice ready for distribution to consumers.

(b) If the facility is producing more than one type of juice covered by this section, processors shall take subsamples according to paragraph (a) of this section for each of the covered juice products produced.

(c) Processors shall analyze each subsample for the presence of *E. coli* by the method entitled "Analysis for *Escherichia coli* in Citrus Juices—Modification of AOAC Official Method 992.30" or another method that is at least equivalent to this method in terms of accuracy, precision, and sensitivity in detecting *E. coli*. This method is designed to detect the presence or absence of *E. coli* in a 20 mL sample of juice (consisting of two 10 mL subsamples). The method is as follows:

(1) *Sample size.* Total-20 mL of juice; perform analysis using two 10 mL aliquots.

(2) *Media.* Universal Preenrichment Broth (Difco, Detroit, MI), EC Broth (various manufacturers).

(3) *Method.* ColiComplete (AOAC Official Method 992.30—modified).

(4) *Procedure.* Perform the following procedure two times:

(i) Aseptically inoculate 10 mL of juice into 90 mL of Universal Preenrichment Broth (Difco) and incubate at 35 °C for 18 to 24 hours.

(ii) Next day, transfer 1 mL of preenriched sample into 10 mL of EC Broth, without durham gas vials. After inoculation, aseptically add a ColiComplete SSD disc into each tube.

(iii) Incubate at 44.5 °C for 18 to 24 hours.

(iv) Examine the tubes under longwave ultra violet light (366 nm). Fluorescent tubes indicate presence of *E. coli*.

(v) MUG positive and negative controls should be used as reference in interpreting fluorescence reactions. Use an *E. coli* for positive control and 2 negative controls—a MUG negative strain and an uninoculated tube media.

(d) If either 10 mL subsample is positive for *E. coli*, the 20 mL sample is recorded as positive and the processor shall:

(1) Review monitoring records for the control measures to attain the 5-log reduction standard and correct those conditions and practices that are not met. In addition, the processor may choose to test the sample for the presence of pathogens of concern.

(2) If the review of monitoring records or the additional testing indicates that the 5-log reduction standard was not achieved (*e.g.*, a sample is found to be positive for the presence of a pathogen or a deviation in the process or its delivery is identified), the processor shall take corrective action as set forth in § 120.10.

(e) If two samples in a series of seven tests are positive for *E. coli*, the control measures to attain the 5-log reduction standard shall be deemed to be inadequate and the processor shall immediately:

(1) Until corrective actions are completed, use an alternative process or processes that achieve the 5-log reduction after the juice has been expressed;

(2) Perform a review of the monitoring records for control measures to attain the 5-log reduction standard. The review shall be sufficiently extensive to determine that there are no trends towards loss of control;

(i) If the conditions and practices are not being met, correct those that do not conform to the HACCP plan; or

(ii) If the conditions and practices are being met, the processor shall validate the HACCP plan in relation to the 5-log reduction standard; and

(3) Take corrective action as set forth in § 120.10. Corrective actions shall include ensuring no product enters commerce that is injurious to health as set forth in § 120.10(a)(1).

Dated: December 20, 2000.

Jane E. Henny,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

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